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P.O. Box 1450
Alexandria, Virginia 22313-1450
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APPLICATION NUMBER	PATENT NUMBER	GROUP ART UNIT	REQUEST ID
14/754,932	9604901	1672	102656

PAIR Correspondence Address/Fee Address Change

The following fields have been changed to Customer Number 166905 on 01/03/2020 via Private PAIR in view of the certification copied below that authorized the change.

- Correspondence Address

The address for Customer Number 166905 is:

166905
Foley & Lardner LLP
3000 K Street N.W.
Suite 600
Washington, DC 20007-5109

I certify, in accordance with 37 CFR 1.4(d)(4) that I am:

An attorney or Agent of Record registered to practice before the Patent and Trademark Office who has been given power of attorney in this application

Signature:	/Stephen B. Maebius/
Name:	Stephen B. Maebius
Registration Number:	35264

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 9,604,901 B2
APPLICATION NO. : 14/754932
DATED : March 28, 2017
INVENTOR(S) : Hitesh Batra et al.

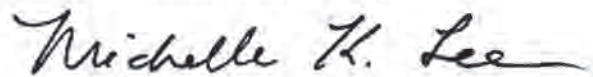
Page 1 of 1

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 17, Claim 1, Line 27, "(c) containing the" should be --(c) contacting the--.

Signed and Sealed this
Sixteenth Day of May, 2017



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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor Name: Hitesh BATRA
Title: AN IMPROVED PROCESS TO PREPARE
TREPROSTINIL, THE ACTIVE INGREDIENT IN
REMODULIN®
Patent. No.: 9,604,901
Issue Date: 3/28/2017
Examiner: Yevgeny Valenrod
Art Unit: 1672
Confirmation Number: 1865

**REQUEST FOR CERTIFICATE OF CORRECTION FOR
PTO MISTAKE PURSUANT TO 37 C.F.R. § 1.322(a)**

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

Commissioner:

Enclosed, is a Certificate of Correction, Form PTO-1050, for United States Patent Number 9,604,901 issued March 28, 2017. The following Patent Office printing error appears in the issued patent:

IN THE CLAIMS

The exact claim and line number where the error in the issued patent is shown correctly in the application file is

Col. 17, claim 1, line 27, "(c) containing the" should be --(c) contacting the--.

-|-

Applicant submits that the above change would not constitute new matter, and correction thereof would not require reexamination.

Pursuant to 37 C.F.R. §1.322, Applicant requests that the enclosed Certificate of Correction be approved.

Although Applicant believes that no fee is required for this Request, the Commissioner is hereby authorized to charge any additional fees which may be required for this Request to Deposit Account No. 19-0741.

Respectfully submitted,

Date APR 11 2017

By 

FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 672-5569
Facsimile: (202) 672-5399

Stephen B. Maebius
Attorney for Applicant
Registration No. 35,264

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. : 9,604,901
 APPLICATION NO. : 14/754932
 DATED : 3/28/2017
 INVENTOR(S) : Hitesh BATRA; Sudersan M. TULADHAR; Raju PENMASTA; David A. WALSH

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:

Col. 17, claim 1, line 27, "(c) containing the" should be --(c) contacting the--.

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

Foley & Lardner LLP
 3000 K Street, N.W., Suite 600
 Washington, D.C. 20007-5109

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.

Electronic Acknowledgement Receipt

EFS ID:	28891657
Application Number:	14754932
International Application Number:	
Confirmation Number:	1865
Title of Invention:	PROCESS TO PREPARE TREPROSTINIL, THE ACTIVE INGREDIENT IN REMODULIN2
First Named Inventor/Applicant Name:	Hitesh Batra
Customer Number:	22428
Filer:	Stephen Bradford Maebius/Karen Strawderman
Filer Authorized By:	Stephen Bradford Maebius
Attorney Docket Number:	080618-1550
Receipt Date:	11-APR-2017
Filing Date:	30-JUN-2015
Time Stamp:	13:22:39
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Request for Certificate of Correction	ReqCOC.pdf	82104 <small>aa621621b4c31705b66d66f1aa81229037a c2897</small>	no	3

Warnings:

Information:	
Total Files Size (in bytes):	82104
<p>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.</p> <p><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.</p> <p><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.</p> <p><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.</p>	



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Table with 5 columns: APPLICATION NO., ISSUE DATE, PATENT NO., ATTORNEY DOCKET NO., CONFIRMATION NO.
Row 1: 14/754,932, 03/28/2017, 9604901, 080618-1550, 1865

22428 7590 03/08/2017
Foley & Lardner LLP
3000 K STREET N.W.
SUITE 600
WASHINGTON, DC 20007-5109

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 Data Management (ODM) at (571)-272-4200.

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

- Hitesh Batra, Herndon, VA;
United Therapeutics Corporation, Silver Spring, MD;
Sudersan M. Tuladhar, Silver Spring, MD;
Raju Pennasta, Herndon, VA;
David A. Walsh, Palmyra, VA;

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.



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NOTICE OF ALLOWANCE AND FEE(S) DUE

22428 7590 02/14/2017
Foley & Lardner LLP
3000 K STREET N.W.
SUITE 600
WASHINGTON, DC 20007-5109

EXAMINER

VALENROD, YEVGENY

ART UNIT PAPER NUMBER

1672

DATE MAILED: 02/14/2017

Table with 5 columns: APPLICATION NO., FILING DATE, FIRST NAMED INVENTOR, ATTORNEY DOCKET NO., CONFIRMATION NO.
14/754,932 06/30/2015 Hitesh Batra 080618-1550 1865

TITLE OF INVENTION: PROCESS TO PREPARE TREPROSTINIL, THE ACTIVE INGREDIENT IN REMODULIN2

Table with 7 columns: APPLN. TYPE, ENTITY STATUS, ISSUE FEE DUE, PUBLICATION FEE DUE, PREV. PAID ISSUE FEE, TOTAL FEE(S) DUE, DATE DUE
nonprovisional UNDISCOUNTED \$960 50 \$960 \$960 05/15/2017

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

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

HOW TO REPLY TO THIS NOTICE:

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

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

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

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

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

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

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

PART B - FEE(S) TRANSMITTAL

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

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

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

22428 7590 02/14/2017
Foley & Lardner LLP
3000 K STREET N.W.
SUITE 600
WASHINGTON, DC 20007-5109

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

Certificate of Mailing or Transmission

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

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

APPLICATION NO: 14/754,932	FILING DATE 06/30/2015	FIRST NAMED INVENTOR Hitesh Batra	ATTORNEY DOCKET NO: 080618-1550	CONFIRMATION NO: 1865
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TITLE OF INVENTION: PROCESS TO PREPARE TREPROSTINIL, THE ACTIVE INGREDIENT IN REMODULIN2

APPLN. TYPE nonprovisional	ENTITY STATUS UNDISCOUNTED	ISSUE FEE DUE \$960	PUBLICATION FEE DUE \$0	PREV. PAID ISSUE FEE \$960	TOTAL FEE(S) DUE \$960	DATE DUE 05/15/2017
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EXAMINER VALENROD, YEVGENY	ART UNIT 1672	CLASS-SUBCLASS 562-466000
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1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

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

2. For printing on the patent front page, list

- (1) The names of up to 3 registered patent attorneys or agents OR, alternatively, 1 _____
- (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. 2 _____
- 3 _____

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

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

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

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

4a. The following fee(s) are submitted:

- Issue Fee
- Publication Fee (No small entity discount permitted)
- Advance Order - # of Copies _____

4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)

- A check is enclosed.
- Payment by credit card. Form PTO-2038 is attached.
- The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

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

- Applicant certifying micro entity status. See 37 CFR 1.29
- 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

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Table with 5 columns: APPLICATION NO., FILING DATE, FIRST NAMED INVENTOR, ATTORNEY DOCKET NO., CONFIRMATION NO.
14/754,932 06/30/2015 Hitesh Batra 080618-1550 1865

22428 7590 02/14/2017
Foley & Lardner LLP
3000 K STREET N.W.
SUITE 600
WASHINGTON, DC 20007-5109

EXAMINER

VALENROD, YEVGENY

ART UNIT PAPER NUMBER

1672

DATE MAILED: 02/14/2017

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

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

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

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

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

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

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

Privacy Act Statement

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

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

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

Notice of Allowability	Application No. 14/754,932	Applicant(s) BATRA ET AL.	
	Examiner YEVGENY VALENROD	Art Unit 1672	AIA (First Inventor to File) Status No

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

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

1. This communication is responsive to RCE filed on 12/21/16.
 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 1,6 and 8-14. 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. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Examiner's Amendment/Comment |
| 2. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ | 6. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| 3. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 7. <input type="checkbox"/> Other _____. |
| 4. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. | |

/YEVGENY VALENROD/
Primary Examiner, Art Unit 1672

Search Notes 	Application/Control No. 14754932	Applicant(s)/Patent Under Reexamination BATRA ET AL.
	Examiner YEVEGENY VALENROD	Art Unit 1672

CPC- SEARCHED		
Symbol	Date	Examiner
C07C 59/72; 51/08; 51/41; 51/412; 213/08; 405/0075	2/9/2017	YV

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
562	466	2/9/2017	YV

SEARCH NOTES		
Search Notes	Date	Examiner
EAST	2/9/2017	YV
Inventor	2/9/2017	YV
C07C 59/72; 51/08; 51/41; 51/412; 213/08; 405/0075	2/9/2017	YV

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner
C07C	59/72; 51/08; 51/41; 51/412; 213/08; 405/0075	2/9/2017	YV
562	466	2/9/2017	YV

	/YEVEGENY VALENROD/ Primary Examiner, Art Unit 1672
--	--

Atty. Dkt. No. 080618-1550

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor Name: Hitesh BATRA
Title: AN IMPROVED PROCESS TO PREPARE
TREPROSTINIL, THE ACTIVE INGREDIENT IN
REMODULIN®
Application No.: 14/754932
Filing Date: 6/30/2015
Examiner: Yevgeny Valenrod
Art Unit: 1672
Confirmation No.: 1865

INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.56

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

Commissioner:

Applicant submits herewith documents for the Examiner's consideration in accordance with 37 CFR §§1.56, 1.97 and 1.98.

Applicant respectfully requests that each listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The submission of any document herewith is not an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a

Atty. Dkt. No. 080618-1550

competent reference any document submitted herewith. However, in accordance with MPEP § 609.04(a)(I), Applicant hereby states that for items for which the date of publication supplied does not include the month of publication, the year of publication is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the particular month of publication is not in issue.

CONCISE EXPLANATION OF RELEVANCE

Invalidity contentions filed against parent U.S. Patent 8,497,393 ("the '393 parent patent") and prior art mentioned therein are being filed in this submission. With respect to certain invalidity contentions that contain "confidential" designations, those documents were previously designated confidential at one time in the litigation, but they are no longer subject to confidentiality, except where certain information has been redacted.

Recent Patent Owner documents are also being cited herein from the related proceeding IPR2016-00006, *Steadymed Ltd. (Petitioner), v. United Therapeutics Corporation (Patent Owner)*, Case IPR2016-00006, US Patent 8,497,393, which involves the same '393 parent patent of the above-captioned patent application. Although these documents were previously submitted, the versions filed with this Statement are new versions of certain documents filed recently in the IPR that have some information unredacted that was previously redacted in prior versions.

Atty. Dkt. No. 080618-1550

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing of a first Office action after the filing of a RCE.

Although Applicant believes that no fee is required, the Commissioner is hereby authorized to charge any additional fees which may be due to Deposit Account Number 19-0741.

Respectfully submitted,

Date Dec. 21, 2016

By /Stephen B. Maebius/

FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 672-5569
Facsimile: (202) 672-5399

Stephen B. Maebius
Attorney for Applicant
Registration No. 35,264

PTO/SB/08 (modified)

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT Date Submitted: December 21, 2016 (use as many sheets as necessary)				Complete if Known	
Sheet	1	of	3	Application Number	14/754932
				Filing Date	6/30/2015
				First Named Inventor	Hitesh BATRA
				Art Unit	1672
				Examiner Name	Yevgeny Valenrod
				Attorney Docket Number	080618-1550

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)				

UNPUBLISHED U.S. PATENT APPLICATION DOCUMENTS						
Examiner Initials*	Cite No. ¹	U.S. Patent Application Document		Filing Date of Cited Document MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Serial Number-Kind Code ² (if known)				

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. ¹	Foreign Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Documents	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³	Number ⁴ Kind Code ⁵ (if known)				

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	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 ⁶
	E1	Petitioner's Demonstratives filed November 28, 2016, in <i>Steadymed Ltd. (Petitioner), v. United Therapeutics Corporation (Patent Owner)</i> , Case IPR2016-00006, US Patent 8,497,393.	
	E2	Patent Owner Response to Petition filed November 23, 2016, in <i>Steadymed Ltd. (Petitioner), v. United Therapeutics Corporation (Patent Owner)</i> , Case IPR2016-00006, US Patent 8,497,393, with Redacted Exhibits 2006, 2020, 2022, 2058 and 2059 filed November 23, 2016, 1151 pages.	

Examiner Signature	Date Considered	
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PTO/SB/08 (modified)

Substitute for form 1449/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	14/754932
				Filing Date	6/30/2015
Date Submitted: December 21, 2016				First Named Inventor	Hitesh BATRA
				Art Unit	1672
(use as many sheets as necessary)				Examiner Name	Yevgeny Valenrod
				Attorney Docket Number	080618-1550
Sheet	2	of	3		

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	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 ⁶
	E3	Patent Owner Demonstratives filed November 23, 2016, in <i>SteadyMed Ltd. (Petitioner), v. United Therapeutics Corporation (Patent Owner)</i> , Case IPR2016-00006, US Patent 8,497,393, 62 pages.	
	E4	Decision Redacted Institute of <i>Inter Partes</i> Review dated November 23, 2016, in <i>SteadyMed Ltd. (Petitioner), v. United Therapeutics Corporation (Patent Owner)</i> , Case IPR2016-00006, US Patent 8,497,393, 53 pages.	
	E5	Service copy of Third Party Submission dated October 16, 2016, filed but not entered in US 14/754,932 on October 16, 2016, with 6 indicated attachments, 822 pages.	
	E6	Redacted Defendant Sandoz Inc.'s Invalidation Contentions dated February 5, 2015, <i>United Therapeutics Corporation (Plaintiff) v. Sandoz Inc. (Defendant)</i> , In The United States District Court for the District of New Jersey, Civil Action No. 3:14-cv-5499(PGH)(LHG), 90 pages.	
	E7	Defendant Sandoz Inc.'s Invalidation Contentions dated February 5, 2015, <i>United Therapeutics Corporation (Plaintiff) v. Sandoz Inc. (Defendant)</i> , In The United States District Court for the District of New Jersey, Civil Action No. 3:14-cv-5499(PGH)(LHG), 189 pages.	
	E8	Defendant Actavis Laboratories FL, Inc. Preliminary Invalidation Contentions, dated August 30, 2016, <i>United Therapeutics Corporation, and Supernus Pharmaceuticals, Inc., (Plaintiff) v. Actavis Laboratories FL, Inc., (Defendant)</i> , In The United States District Court for the District of New Jersey, Civil Action No. 3:16-cv-01816-PGS-LHG, Civil Action No. 3:16-cv-03642-PGS-LHG, 330 pages, (see particularly pages 18-20, 42-62 and 269-280).	
	E9	Exhibit G, Invalidation Claim Chart for the '393 patent, January 12, 2015, 66 pages.	
	E10	Defendant Teva Pharmaceuticals USA, Inc.'s Amended Non-Infringement and Invalidation Contentions, dated April 24, 2015, <i>United Therapeutics Corporation (Plaintiff) v. Teva Pharmaceuticals USA, Inc. (Defendant)</i> , In The United States District Court for the District of New Jersey, Civil Action No. 3:14-cv-05498(PGS)(LHG), 94 pages, (see particularly pages 22-54).	
	E11	Arumugan et al., "A New Purification Process for Pharmaceutical and Chemical Industries," <i>Organic Process Research & Development</i> , 2005, 9:319-320.	
	E12	Burk et al., "An Enantioselective Synthesis of (S)-(+)-3-Aminomethyl-5-methylhexanoic Acid via Asymmetric Hydrogenation," <i>J. Org. Chem.</i> , 2003, 68:5731-5734.	
	E13	Eliel et al., <i>Stereochemistry of Organic Compounds</i> , 1994, 322-325.	
	E14	Harwood et al., <i>Experimental organic chemistry: Principles and Practice</i> , 1989, 127-134.	
	E15	Jones, Maitland Jr., <i>Organic Chemistry</i> , 2 nd Ed., 2000, 153-155.	
	E16	Lin et al., "Benzindene Prostaglandins. Synthesis of Optically Pure 15-Deoxy-U-68,215 and Its Enantiomer via a Modified Intramolecular Wadsworth-Emmons-Wittig Reaction," <i>J. Org. Chem.</i> , 1987, 52:5594-5601.	
	E17	McManus et al., "Tetrazole Analogs of Plant Auxins," <i>J. Org. Chem.</i> , 1959, 24:1464-1467.	
	E18	Monson, Richard S., <i>Advanced Organic Synthesis, Methods and Techniques</i> , 1971, 178-188.	

Examiner Signature	Date Considered	
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4848-0394-1950.1

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /Y.V/

Substitute for form 1449/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Application Number	14/754932
		Filing Date	6/30/2015
Date Submitted: December 21, 2016		First Named Inventor	Hitesh BATRA
		Art Unit	1672
(use as many sheets as necessary)		Examiner Name	Yevgeny Valenrod
		Attorney Docket Number	080618-1550
Sheet	3	of	3

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	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 ^a
	E19	Ohno et al., "Development of Dual-Acting Benzofurans for Thromboxane A2 Receptor Antagonist and Prostacyclin Receptor Agonist: Synthesis, Structure-Activity Relationship, and Evaluation of Benzofuran Derivatives," J. Med. Chem., 2005, 48:5279-5294.	
	E20	Olmsted III et al., Chemistry, The Molecular Science, Mosby-Year Book, Inc., Chapter 10 "Effects of Intermolecular Forces," 1994, 428-486.	
	E21	Pavia et al., Introduction to Organic Laboratory Techniques, First Edition, 1998, 648.	
	E22	Physicians' Desk Reference, 59 Edition, 2005, for Bicillin® L-A (penicillin G benzathine suspension), 5 pages.	
	E23	Priscinzano et al., "Piperidine Analogues of 1-[2-[Bis(4-fluorophenyl)methoxy]ethyl]-4-(3-phenylpropyl)piperazine (GBR 12909): High Affinity Ligands for the Dopamine Transporter," J. Med. Chem., 2002, 45:4371-4374.	
	E24	REMODULIN® label, 2014, 17 pages.	
	E25	Schoffstall, et al., Microscale and Miniscale Organic Chemistry Laboratory Experiments, 2004, 2 nd Ed., 200-202.	
	E26	Sorrell, Thomas N., Organic Chemistry, 1999, 755-758.	
	E27	Wiberg, Laboratory Technique in Organic Chemistry, 1960, 112.	
	E28	Yu et al., "Novel Synthetic Route of a Pivotal Intermediate for the Synthesis of 1 β -Methyl Carbapenem Antibiotics," Organic Process Research & Development, 2006,10:829-832.	

Examiner Signature	/YEVGENY VALENROD/	Date Considered	02/09/2017
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Substitute for form 1449/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Application Number	14/754932
Date Submitted: <u>JAN 10 2017</u>		Filing Date	6/30/2015
<i>(use as many sheets as necessary)</i>		First Named Inventor	Hitesh BATRA
Sheet	1	Art Unit	1672
	of	Examiner Name	Yevgeny Valenrod
	1	Attorney Docket Number	080618-1550

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Documents	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	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 ⁶

Examiner Signature	/YEVGENY VALENROD/	Date Considered	02/09/2017
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Index of Claims 	Application/Control No. 14754932	Applicant(s)/Patent Under Reexamination BATRA ET AL.
	Examiner YEVEGENY VALENROD	Art Unit 1672

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

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

CLAIM		DATE							
Final	Original	07/28/2015	09/10/2015	02/04/2016	10/14/2016	11/04/2016	02/09/2017		
1	1	✓	=	✓	=	=	=		
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	3	✓	=	✓	-	-	-		
	4	✓	-	-	-	-	-		
	5	✓	-	-	-	-	-		
2	6	✓	=	✓	=	=	=		
	7	✓	-	-	-	-	-		
3	8	✓	=	✓	=	=	=		
4	9			✓	=	=	=		
5	10			✓	=	=	=		
6	11			✓	=	=	=		
7	12			✓	=	=	=		
8	13			✓	✓	=	=		
9	14			✓	✓	=	=		

EAST Search History (Prior Art)


Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	1	("8497393").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2017/02/09 06:34
L2	1	("8242305").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2017/02/09 06:34
L3	1	("4683330").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2017/02/09 06:34
L4	1	("4306075").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2017/02/09 06:34
L5	32	((Hitesh) near2 (Batra)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2017/02/09 06:34
L6	24	((Sudersan) near2 (Tuladhar)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2017/02/09 06:34
L7	30	((Raju) near2 (Penmasta)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2017/02/09 06:34
L8	248	((David) near2 (Walsh)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2017/02/09 06:34
L9	276	L5 or L6 or L7 or L8	US-PGPUB; USPAT; USOCR	OR	ON	2017/02/09 06:34
L10	24	L9 and treprostinil	US-PGPUB; USPAT; USOCR	OR	ON	2017/02/09 06:34
L11	540	c07c59/72.cpc.	US-PGPUB; USPAT; USOCR	OR	ON	2017/02/09 06:34
L12	870	(562/466).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2017/02/09 06:34
L13	1283	L11 or L12	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2017/02/09 06:34
L14	47	L13 and treprostinil	US-PGPUB; USPAT; USOCR	OR	ON	2017/02/09 06:34

EAST Search History (Prior Art)

L15	42	L14 and purity	US-PGPUB; USPAT; USOCR	OR	ON	2017/02/09 06:34
L16	38	L15 and HPLC	US-PGPUB; USPAT; USOCR	OR	ON	2017/02/09 06:34
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L18	2	wo "2005007081"	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2017/02/09 06:34
L19	4	"9242350"	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2017/02/09 06:34
L20	1	("8242305").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2017/02/09 06:34
L21	1	("9156786").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2017/02/09 06:34

EAST Search History (Interference)


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Issue Classification 	Application/Control No. 14754932	Applicant(s)/Patent Under Reexamination BATRA ET AL.
	Examiner YEVEGENY VALENROD	Art Unit 1672

CPC						
Symbol					Type	Version
C07C	59	/	72		F	2013-01-01
C07C	51	/	08		I	2013-01-01
C07C	51	/	41		I	2013-01-01
C07C	51	/	412		I	2013-01-01
C07C	213	/	08		I	2013-01-01
C07C	405	/	0075		I	2013-01-01
A01N	37	/	10		A	2013-01-01
C07C	39	/	12		A	2013-01-01
C07C	39	/	17		A	2013-01-01
C07C	59	/	60		A	2013-01-01
		/				
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		/				
		/				


CPC Combination Sets							
Symbol				Type	Set	Ranking	Version
C07C	51	/	08	I	1	1	2013-01-01
C07C	59	/	72	I	1	2	2013-01-01
C07C	51	/	412	I	2	1	2013-01-01
C07C	59	/	72	I	2	2	2013-01-01

NONE		Total Claims Allowed:	
		9	
(Assistant Examiner)	(Date)	O.G. Print Claim(s)	O.G. Print Figure
YEVEGENY VALENROD/ Primary Examiner, Art Unit 1672	02/09/2017	1	none
(Primary Examiner)	(Date)		

Issue Classification 	Application/Control No. 14754932	Applicant(s)/Patent Under Reexamination BATRA ET AL.
	Examiner YEVEGENY VALENROD	Art Unit 1672

US ORIGINAL CLASSIFICATION						INTERNATIONAL CLASSIFICATION								
CLASS			SUBCLASS			CLAIMED				NON-CLAIMED				
562			466			C	0	7	C	59172 (2006.01.01)				
CROSS REFERENCE(S)														
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)													

NONE		Total Claims Allowed:	
		9	
(Assistant Examiner)	(Date)	O.G. Print Claim(s)	O.G. Print Figure
YEVEGENY VALENROD/ Primary Examiner, Art Unit 1672	02/09/2017	1	none
(Primary Examiner)	(Date)		

Issue Classification 	Application/Control No. 14754932	Applicant(s)/Patent Under Reexamination BATRA ET AL.
	Examiner YEVEGENY VALENROD	Art Unit 1672

<input type="checkbox"/> Claims renumbered in the same order as presented by applicant		<input type="checkbox"/> CPA		<input checked="" type="checkbox"/> T.D.		<input type="checkbox"/> R.1.47									
Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
1	1														
2	6														
3	8														
4	9														
5	10														
6	11														
7	12														
8	13														
9	14														

NONE		Total Claims Allowed:	
(Assistant Examiner)		9	
(Date)			
YEVEGENY VALENROD/ Primary Examiner, Art Unit 1672		O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)		1	none
(Date)		02/09/2017	

PART B - FEE(S) TRANSMITTAL

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

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

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

22428 7590 02/14/2017
Foley & Lardner LLP
3000 K STREET N.W.
SUITE 600
WASHINGTON, DC 20007-5109

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

Certificate of Mailing or Transmission

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

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

APPLICATION NO: 14/754,932	FILING DATE 06/30/2015	FIRST NAMED INVENTOR Hitesh Batra	ATTORNEY DOCKET NO: 080618-1550	CONFIRMATION NO: 1865
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TITLE OF INVENTION: PROCESS TO PREPARE TREPROSTINIL, THE ACTIVE INGREDIENT IN REMODULIN2

APPLN. TYPE nonprovisional	ENTITY STATUS UNDISCOUNTED	ISSUE FEE DUE \$960	PUBLICATION FEE DUE \$0	PREV. PAID ISSUE FEE \$960	TOTAL FEE(S) DUE XXXXX \$0	DATE DUE 05/15/2017
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EXAMINER VALENROD, YEVGENY	ART UNIT 1672	CLASS-SUBCLASS 562-466000
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1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

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

2. For printing on the patent front page, list

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

1 **Foley & Lardner 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 has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

United Therapeutics Corporation

Silver Spring, MD

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

4a. The following fee(s) are submitted:

- Issue Fee
- Publication Fee (No small entity discount permitted)
- Advance Order - # of Copies _____

4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)

- A check is enclosed.
- Payment by credit card. Form PTO-2038 is attached.
- The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number 19-0741 (enclose an extra copy of this form).

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

- Applicant certifying micro entity status. See 37 CFR 1.29
- 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 /Stephen B. Maebius/

Date February 14, 2017

Typed or printed name Stephen B. Maebius

Registration No. 35,264

Electronic Acknowledgement Receipt

EFS ID:	28349554
Application Number:	14754932
International Application Number:	
Confirmation Number:	1865
Title of Invention:	PROCESS TO PREPARE TREPROSTINIL, THE ACTIVE INGREDIENT IN REMODULIN2
First Named Inventor/Applicant Name:	Hitesh Batra
Customer Number:	22428
Filer:	Stephen Bradford Maebius/Karen Strawderman
Filer Authorized By:	Stephen Bradford Maebius
Attorney Docket Number:	080618-1550
Receipt Date:	14-FEB-2017
Filing Date:	30-JUN-2015
Time Stamp:	13:41:58
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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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)	IFTM.pdf	124943 059e7c22e8f5e172a1531d9112dccc85a0c2ed	no	1

Warnings:

Information:	
Total Files Size (in bytes):	124943
<p>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.</p> <p><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.</p> <p><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.</p> <p><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.</p>	

PART B - FEE(S) TRANSMITTAL

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

JFW

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)

22428 7590 02/14/2017
 Foley & Lardner LLP
 3000 K STREET N.W.
 SUITE 600
 WASHINGTON, DC 20007-5109



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

Certificate of Mailing or Transmission

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

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/754,932	06/30/2015	Hitesh Batra	080618-1550	1865

TITLE OF INVENTION: PROCESS TO PREPARE TREPROSTINIL, THE ACTIVE INGREDIENT IN REMODULIN2

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	\$960	\$0	\$960	XXXXX \$0	05/15/2017

EXAMINER	ART UNIT	CLASS-SUBCLASS	02/16/2017 MBLANCO1 00000017 14754932
VALENROD, YEVGENY	1672	562-466000	01 FC:1501 960.00 OP

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

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

1. Foley & Lardner 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 has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE: United Therapeutics Corporation
 (B) RESIDENCE: (CITY and STATE OR COUNTRY) Silver Spring, MD

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

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

4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)
 A check is enclosed.
 Payment by credit card. Form PTO-2038 is attached.
 The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number 19-0741 (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)
 Applicant certifying micro entity status. See 37 CFR 1.29
 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: /Stephen B. Maebius/
 Typed or printed name: Stephen B. Maebius

Adjusted date: 02/16/2017 MBLANCO1
 Date: 11/14/2016 INTP SW 2017339 14754932 -960.00 OP
 01 FC:1501
 Registration No. 35,264

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor Name: Hitesh BATRA
Title: AN IMPROVED PROCESS TO PREPARE TREPROSTINIL,
THE ACTIVE INGREDIENT IN REMODULIN®
Appl. No.: 14/754,932
Filing Date: 6/30/2015
Examiner: Yevgeny Valenrod
Art Unit: 1672
Confirmation Number: 1865

NOTIFICATION OF RELATED PROCEEDINGS

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

Commissioner:

Applicant hereby provides UTC's Responses to Invalidity Contentions against US Patent 8,497,393 ("the '393 patent"), which is the issued parent of the above-captioned patent application, from the following proceedings:

United Therapeutics Corp. (Plaintiff and Counterclaim-Defendant) v. Sandoz, Inc. (Defendant and Counterclaim-Plaintiff), Civil Action No. 3:14-cv-05499-PGS-LHG;

United Therapeutics Corp. (Plaintiff and Counterclaim-Defendant) v. Teva Pharmaceuticals USA, Inc. (Defendant and Counterclaim-Plaintiff), Civil Action No. 3:14-cv-05498-PGS-LHG;

United Therapeutics Corp. (Plaintiff and Counterclaim-Defendant) v. Watson Laboratories, Inc. (Defendant and Counterclaim-Plaintiff), Civil Action No. 3:15-cv-05723-PGS-LHG; and

United Therapeutics Corporation and Supernus Pharmaceuticals, Inc. (Plaintiffs) v. Actavis Laboratories FL, Inc. (Defendant), C.A. No. 16-cv-01816 (PGS)(LHG), C.A. No. 16-cv-03642 (PGS)(LHG).

The purpose of this notice is to provide plaintiff UTC's responses to the invalidity contentions submitted with the recently filed Information Disclosure Statements. Certain confidential information has been redacted, as well as information not related to the '393 patent.

Respectfully submitted,

Date Jan. 10, 2017

By Stephen B. Maebius/

FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 672-5569
Facsimile: (202) 672-5399

Stephen B. Maebius
Attorney for Applicant
Registration No. 35,264

Electronic Acknowledgement Receipt

EFS ID:	28022586
Application Number:	14754932
International Application Number:	
Confirmation Number:	1865
Title of Invention:	PROCESS TO PREPARE TREPROSTINIL, THE ACTIVE INGREDIENT IN REMODULIN2
First Named Inventor/Applicant Name:	Hitesh Batra
Customer Number:	22428
Filer:	Stephen Bradford Maebius/Karen Strawderman
Filer Authorized By:	Stephen Bradford Maebius
Attorney Docket Number:	080618-1550
Receipt Date:	10-JAN-2017
Filing Date:	30-JUN-2015
Time Stamp:	14:36:40
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Miscellaneous Incoming Letter	NtfRltProc.pdf	52080 <small>8587160f1c896991f0d4e092c15223162f6796e15</small>	no	2

Warnings:

Substitute for form 1449/PTO			Complete if Known		
INFORMATION DISCLOSURE STATEMENT BY APPLICANT			Application Number	14/754932	
Date Submitted: <u>JAN 10 2017</u>			Filing Date	6/30/2015	
<i>(use as many sheets as necessary)</i>			First Named Inventor	Hitesh BATRA	
			Art Unit	1672	
			Examiner Name	Yevgeny Valenrod	
Sheet	1	of 1	Attorney Docket Number	080618-1550	

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² <i>(if known)</i>			

FOREIGN PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Documents	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Country Code ³ Number ⁴ Kind Code ⁵ <i>(if known)</i>			

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	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 ⁶
	F1	Redacted Defendant Watson Laboratories, Inc.'s Invalidation Contentions dated December 11, 2015, <i>United Therapeutics Corporation (Plaintiff) v. Watson Laboratories, Inc. (Defendant)</i> , In The United States District Court for the District of New Jersey, Civil Action No. 3:15-cv-05723-PGS-LHG, 35 pages.	

Examiner Signature	Date Considered
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Electronic Acknowledgement Receipt

EFS ID:	28022644
Application Number:	14754932
International Application Number:	
Confirmation Number:	1865
Title of Invention:	PROCESS TO PREPARE TREPROSTINIL, THE ACTIVE INGREDIENT IN REMODULIN2
First Named Inventor/Applicant Name:	Hitesh Batra
Customer Number:	22428
Filer:	Stephen Bradford Maebius/Karen Strawderman
Filer Authorized By:	Stephen Bradford Maebius
Attorney Docket Number:	080618-1550
Receipt Date:	10-JAN-2017
Filing Date:	30-JUN-2015
Time Stamp:	14:38:45
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		IDS.pdf	155124 <small>03b92f1x1b035:949efc5c0ee5f65b2887 88624</small>	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	Other Reference-Patent/App/Search documents	WatsonInvContRedacted.pdf	352468	no	35
Warnings:					
Information:					
Total Files Size (in bytes):			507592		
<p>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.</p> <p><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.</p> <p><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.</p> <p><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.</p>					

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor Name: Hitesh BATRA
Title: AN IMPROVED PROCESS TO PREPARE
TREPASTINIL, THE ACTIVE INGREDIENT IN
REMODULIN®
Application No.: 14/754932
Filing Date: 6/30/2015
Examiner: Yevgeny Valenrod
Art Unit: 1672
Confirmation No.: 1865

INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.56

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

Commissioner:

Applicant submits herewith documents for the Examiner's consideration in accordance with 37 CFR §§1.56, 1.97 and 1.98.

Applicant respectfully requests that each listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The submission of any document herewith is not an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a

competent reference any document submitted herewith. However, in accordance with MPEP § 609.04(a)(1), Applicant hereby states that for items for which the date of publication supplied does not include the month of publication, the year of publication is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the particular month of publication is not in issue.

CONCISE EXPLANATION OF RELEVANCE

An invalidity contention filed against parent U.S. Patent 8,497,393 is filed with this submission. Information not related to the '393 patent has been redacted.

TIMING OF THE DISCLOSURE

The listed document is being submitted in compliance with 37 CFR §1.97(b), before the mailing of a first Office action after the filing of a RCE.

Although Applicant believes that no fee is required, the Commissioner is hereby authorized to charge any additional fees which may be due to Deposit Account Number 19-0741.

Respectfully submitted,

Date Jan. 10, 2017

By /Stephen B. Maebius/

FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 672-5569
Facsimile: (202) 672-5399

Stephen B. Maebius
Attorney for Applicant
Registration No. 35,264

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor Name: Hitesh BATRA
Title: AN IMPROVED PROCESS TO PREPARE
TREPROSTINIL, THE ACTIVE INGREDIENT IN
REMODULIN®
Appl. No.: 14/754932
Appl. Filing Date: 6/30/2015
Examiner: Yevgeny Valenrod
Art Unit: 1672
Confirmation Number: 1865

**REQUEST FOR CONTINUED EXAMINATION (RCE)
TRANSMITTAL**

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

Commissioner:

This is a Request for Continued Examination (RCE) under 37 C.F.R. § 1.114 of the above-identified application. This RCE and the enclosed items listed below are being filed prior to the earliest of: (1) payment of the issue fee (unless a petition under 37 C.F.R. § 1.313 is granted); (2) abandonment of the application; or (3) the filing of a notice of appeal to the U.S. Court of Appeals for the Federal Circuit under 35 U.S.C. §141, or the commencement of a civil action under 35 U.S.C. §145 or §146 (unless the appeal or civil action is terminated).

1. Submission **required** under 37 C.F.R. §1.114: (check items that apply)

a. Previously submitted:

-|-

- Please enter and consider the amendment and/or reply previously filed on __.
 - Please consider the Affidavit(s)/Declaration(s) previously filed on __ but not considered.
 - Please consider the arguments in the Appeal Brief or Reply previously filed on __.
 - Other Documents.
- b. Enclosed are:
- Amendment/Reply.
 - Affidavit(s)/Declaration(s).
 - Information Disclosure Statement.
 - Form PTO/SB/08 with copies of listed references.
 - PTO/SB/424 - Request for Prioritized Examination.
 - Other Documents

Miscellaneous:

- Suspension of action of the above-identified application is requested under 37 C.F.R. § 1.103(c) for a period of __ months.

The filing fee is calculated below at the large entity rate:

	Claims as Amended	Previously Paid For	Extra Claims Present	Rate	Fee Totals
RCE Fee 1.17(e):				\$1,700.00	= \$1,700.00
				0	
Total Claims:	9	-	20 = 0	x \$80.00	= \$0.00
Independents	1	-	3 = 0	x \$420.00	= \$0.00
First presentation of any Multiple Dependent Claims:				+ \$780.00	= \$0.00
CLAIMS FEE TOTAL:					= \$1,700.00

Applicant hereby petitions for an extension of time under 37 C.F.R. §1.136(a) for the total number of months checked below:

<input type="checkbox"/> Extension for response filed within the first month:	\$200.00	0	\$0.00
<input type="checkbox"/> Extension for response filed within the second month:	\$600.00		\$0.00
<input type="checkbox"/> Extension for response filed within the third month:	\$1,400.00		\$0.00
<input type="checkbox"/> Extension for response filed within the fourth month:	\$2,200.00		\$0.00
<input type="checkbox"/> Extension for response filed within the fifth month:	\$3,000.00		\$0.00
EXTENSION FEE SUBTOTAL:			\$0.00
EXTENSION FEE ALREADY PAID:			- \$0.00
EXTENSION FEE TOTAL			\$0.00
CLAIMS AND EXTENSION FEE TOTAL:			\$1,700.00
Prioritized Examination fee (Track I) under 37 C.F.R. § 1.17 (c)			\$0.00
Processing Fee (Track I) under 37 C.F.R. § 1.17 (i)			\$0.00
Publication Fee			\$0.00
<input type="checkbox"/> Suspension of action requested under 37 C.F.R. § 1.103(c)			\$0.00
TOTAL FEE:			\$1,700.00

The above-identified fees of \$1,700.00 are being paid by credit card via EFS-Web.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1,17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Please direct all correspondence to the undersigned attorney or agent at the address indicated below.

Respectfully submitted,

Date Dec. 21, 2016

By /Stephen B. Maebius/

FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 672-5569
Facsimile: (202) 672-5399

Stephen B. Maebius
Attorney for Applicant
Registration No. 35,264

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor Name: Hitesh BATRA
Title: AN IMPROVED PROCESS TO PREPARE
TREPROSTINIL, THE ACTIVE INGREDIENT IN
REMODULIN®
Application No.: 14/754932
Filing Date: 6/30/2015
Examiner: Yevgeny Valenrod
Art Unit: 1672
Confirmation No.: 1865

INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.56

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

Commissioner:

Applicant submits herewith documents for the Examiner's consideration in accordance with 37 CFR §§1.56, 1.97 and 1.98.

Applicant respectfully requests that each listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The submission of any document herewith is not an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a

competent reference any document submitted herewith. However, in accordance with MPEP § 609.04(a)(I), Applicant hereby states that for items for which the date of publication supplied does not include the month of publication, the year of publication is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the particular month of publication is not in issue.

CONCISE EXPLANATION OF RELEVANCE

Invalidity contentions filed against parent U.S. Patent 8,497,393 (“the ‘393 parent patent”) and prior art mentioned therein are being filed in this submission. With respect to certain invalidity contentions that contain “confidential” designations, those documents were previously designated confidential at one time in the litigation, but they are no longer subject to confidentiality, except where certain information has been redacted.

Recent Patent Owner documents are also being cited herein from the related proceeding IPR2016-00006, *Steadymed Ltd. (Petitioner), v. United Therapeutics Corporation (Patent Owner)*, Case IPR2016-00006, US Patent 8,497,393, which involves the same ‘393 parent patent of the above-captioned patent application. Although these documents were previously submitted, the versions filed with this Statement are new versions of certain documents filed recently in the IPR that have some information unredacted that was previously redacted in prior versions.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing of a first Office action after the filing of a RCE.

Although Applicant believes that no fee is required, the Commissioner is hereby authorized to charge any additional fees which may be due to Deposit Account Number 19-0741.

Respectfully submitted,

Date Dec. 21, 2016

By /Stephen B. Maebius/

FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 672-5569
Facsimile: (202) 672-5399

Stephen B. Maebius
Attorney for Applicant
Registration No. 35,264

Substitute for form 1449/PTO			Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT			Application Number	14/754932
Date Submitted: December 21, 2016			Filing Date	6/30/2015
<i>(use as many sheets as necessary)</i>			First Named Inventor	Hitesh BATRA
Sheet 1 of 3			Art Unit	1672
			Examiner Name	Yevgeny Valenrod
			Attorney Docket Number	080618-1550

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² <i>(if known)</i>			

UNPUBLISHED U.S. PATENT APPLICATION DOCUMENTS					
Examiner Initials*	Cite No. ¹	U.S. Patent Application Document	Filing Date of Cited Document MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Serial Number-Kind Code ² <i>(if known)</i>			

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Documents	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ <i>(if known)</i>				

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	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 ⁶
	E2	Patent Owner Response to Petition filed November 23, 2016, in <i>Steadymed Ltd. (Petitioner), v. United Therapeutics Corporation (Patent Owner)</i> , Case IPR2016-00006, US Patent 8,497,393, with Redacted Exhibits 2006, 2020, 2022, 2058 and 2059 filed November 23, 2016, 1151 pages.	

Examiner Signature	Date Considered	
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Substitute for form 1449/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	14/754932
				Filing Date	6/30/2015
Date Submitted: December 21, 2016				First Named Inventor	Hitesh BATRA
				Art Unit	1672
(use as many sheets as necessary)				Examiner Name	Yevgeny Valenrod
				Attorney Docket Number	080618-1550
Sheet	2	of	3		

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	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 ⁶
	E3	Patent Owner Demonstratives filed November 23, 2016, in <i>Steadymed Ltd. (Petitioner), v. United Therapeutics Corporation (Patent Owner)</i> , Case IPR2016-00006, US Patent 8,497,393, 62 pages.	
	E4	Decision Redacted Institute of <i>Inter Partes</i> Review dated November 23, 2016, in <i>Steadymed Ltd. (Petitioner), v. United Therapeutics Corporation (Patent Owner)</i> , Case IPR2016-00006, US Patent 8,497,393, 53 pages.	
	E5	Service copy of Third Party Submission dated October 16, 2016, filed but not entered in US 14/754,932 on October 16, 2016, with 6 indicated attachments, 822 pages.	
	E6	Redacted Defendant Sandoz Inc.'s Invalidation Contentions dated February 5, 2015, <i>United Therapeutics Corporation (Plaintiff) v. Sandoz Inc. (Defendant)</i> , In The United States District Court for the District of New Jersey, Civil Action No. 3:14-cv-5499(PGH)(LHG), 90 pages.	
	E7	Defendant Sandoz Inc.'s Invalidation Contentions dated February 5, 2015, <i>United Therapeutics Corporation (Plaintiff) v. Sandoz Inc. (Defendant)</i> , In The United States District Court for the District of New Jersey, Civil Action No. 3:14-cv-5499(PGH)(LHG), 189 pages.	
	E8	Defendant Actavis Laboratories FL, Inc. Preliminary Invalidation Contentions, dated August 30, 2016, <i>United Therapeutics Corporation, and Supernus Pharmaceuticals, Inc., (Plaintiff) v. Actavis Laboratories FL, Inc., (Defendant)</i> , In The United States District Court for the District of New Jersey, Civil Action No. 3:16-cv-01816-PGS-LHG, Civil Action No. 3:16-cv-03642-PGS-LHG, 330 pages, (see particularly pages 18-20, 42-62 and 269-280).	
	E9	Exhibit G, Invalidation Claim Chart for the '393 patent, January 12, 2015, 66 pages.	
	E10	Defendant Teva Pharmaceuticals USA, Inc.'s Amended Non-Infringement and Invalidation Contentions, dated April 24, 2015, <i>United Therapeutics Corporation (Plaintiff) v. Teva Pharmaceuticals USA, Inc. (Defendant)</i> , In The United States District Court for the District of New Jersey, Civil Action No. 3:14-cv-05498(PGS)(LHG), 94 pages, (see particularly pages 22-54).	
	E11	Arumugan et al., "A New Purification Process for Pharmaceutical and Chemical Industries," <i>Organic Process Research & Development</i> , 2005, 9:319-320.	
	E12	Burk et al., "An Enantioselective Synthesis of (S)-(+)-3-Aminomethyl-5-methylhexanoic Acid via Asymmetric Hydrogenation," <i>J. Org. Chem.</i> , 2003, 68:5731-5734.	
	E13	Eliel et al., <i>Stereochemistry of Organic Compounds</i> , 1994, 322-325.	
	E14	Harwood et al., <i>Experimental organic chemistry: Principles and Practice</i> , 1989, 127-134.	
	E15	Jones, Maitland Jr., <i>Organic Chemistry</i> , 2 nd Ed., 2000, 153-155.	
	E16	Lin et al., "Benzindene Prostaglandins. Synthesis of Optically Pure 15-Deoxy-U-68,215 and Its Enantiomer via a Modified Intramolecular Wadsworth-Emmons-Wittig Reaction," <i>J. Org. Chem.</i> , 1987, 52:5594-5601.	
	E17	McManus et al., "Tetrazole Analogs of Plant Auxins," <i>J. Org. Chem.</i> , 1959, 24:1464-1467.	
	E18	Monson, Richard S., <i>Advanced Organic Synthesis, Methods and Techniques</i> , 1971, 178-188.	

Examiner Signature	Date Considered
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Substitute for form 1449/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Application Number	14/754932
		Filing Date	6/30/2015
Date Submitted: December 21, 2016 <i>(use as many sheets as necessary)</i>		First Named Inventor	Hitesh BATRA
		Art Unit	1672
Sheet 3 of 3		Examiner Name	Yevgeny Valenrod
		Attorney Docket Number	080618-1550

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	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 ^a
	E19	Ohno et al., "Development of Dual-Acting Benzofurans for Thromboxane A2 Receptor Antagonist and Prostacyclin Receptor Agonist: Synthesis, Structure-Activity Relationship, and Evaluation of Benzofuran Derivatives," J. Med. Chem., 2005, 48:5279-5294.	
	E20	Olmsted III et al., Chemistry, The Molecular Science, Mosby-Year Book, Inc., Chapter 10 "Effects of Intermolecular Forces," 1994, 428-486.	
	E21	Pavia et al., Introduction to Organic Laboratory Techniques, First Edition, 1998, 648.	
	E22	Physicians' Desk Reference, 59 Edition, 2005, for Bicillin® L-A (penicillin G benzathine suspension), 5 pages.	
	E23	Priscinzano et al., "Piperidine Analogues of 1-[2-[Bis(4-fluorophenyl)methoxy]ethyl]-4-(3-phenylpropyl)piperazine (GBR 12909): High Affinity Ligands for the Dopamine Transporter," J. Med. Chem., 2002, 45:4371-4374.	
	E24	REMODULIN® label, 2014, 17 pages.	
	E25	Schoffstall, et al., Microscale and Miniscale Organic Chemistry Laboratory Experiments, 2004, 2 nd Ed., 200-202.	
	E26	Sorrell, Thomas N., Organic Chemistry, 1999, 755-758.	
	E27	Wiberg, Laboratory Technique in Organic Chemistry, 1960, 112.	
	E28	Yu et al., "Novel Synthetic Route of a Pivotal Intermediate for the Synthesis of 1 β -Methyl Carbapenem Antibiotics," Organic Process Research & Development, 2006,10:829-832.	

Examiner Signature		Date Considered	
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Document code: WFEE

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Table with 5 columns: APPLICATION NO., ISSUE DATE, PATENT NO., ATTORNEY DOCKET NO., CONFIRMATION NO.
Row 1: 14/754,932, 12/27/2016, 9527794, 080618-1550, 1865

22428 7590 12/07/2016
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3000 K STREET N.W.
SUITE 600
WASHINGTON, DC 20007-5109

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 Data Management (ODM) at (571)-272-4200.

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

Hitesh Batra, Herndon, VA;
United Therapeutics Corporation, Silver Spring, MD;
Sudersan M. Tuladhar, Silver Spring, MD;
Raju Pennasta, Herndon, VA;
David A. Walsh, Palmyra, VA;

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Complete and send this form, together with applicable fee(s), to: **Mail** Mail Stop ISSUE FEE
Commissioner for Patents
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I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

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

APPLICATION NO: 14/754,932	FILING DATE 06/30/2015	FIRST NAMED INVENTOR Hitesh Batra	ATTORNEY DOCKET NO: 080618-1550	CONFIRMATION NO: 1865
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TITLE OF INVENTION: PROCESS TO PREPARE TREPROSTINIL, THE ACTIVE INGREDIENT IN REMODULIN2

APPLN. TYPE nonprovisional	ENTITY STATUS UNDISCOUNTED	ISSUE FEE DUE \$960	PUBLICATION FEE DUE \$0	PREV. PAID ISSUE FEE \$0	TOTAL FEE(S) DUE \$960	DATE DUE 02/09/2017
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EXAMINER VALENROD, YEVGENY	ART UNIT 1672	CLASS-SUBCLASS 562-466000
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1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

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

2. For printing on the patent front page, list

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

1 **Foley & Lardner LLP**

2 _____

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

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

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

United Therapeutics Corporation

Silver Spring, MD

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

4a. The following fee(s) are submitted:

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 The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number 19-0741 (enclose an extra copy of this form).

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- 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 /Stephen B. Maebius/

Date Nov. 10, 2016

Typed or printed name Stephen B. Maebius

Registration No. 35264

Electronic Patent Application Fee Transmittal

Application Number:	14754932			
Filing Date:	30-Jun-2015			
Title of Invention:	PROCESS TO PREPARE TREPROSTINIL, THE ACTIVE INGREDIENT IN REMODULIN2			
First Named Inventor/Applicant Name:	Hitesh Batra			
Filer:	Stephen Bradford Maebius			
Attorney Docket Number:	080618-1550			
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	960	960

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Extension-of-Time:				
Miscellaneous:				
Total in USD (\$)				960

Electronic Acknowledgement Receipt

EFS ID:	27477347
Application Number:	14754932
International Application Number:	
Confirmation Number:	1865
Title of Invention:	PROCESS TO PREPARE TREPROSTINIL, THE ACTIVE INGREDIENT IN REMODULIN2
First Named Inventor/Applicant Name:	Hitesh Batra
Customer Number:	22428
Filer:	Stephen Bradford Maebius/Karen Strawderman
Filer Authorized By:	Stephen Bradford Maebius
Attorney Docket Number:	080618-1550
Receipt Date:	10-NOV-2016
Filing Date:	30-JUN-2015
Time Stamp:	16:28:21
Application Type:	Utility under 35 USC 111(a)

Payment information:

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Payment Type	CARD
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1	Issue Fee Payment (PTO-85B)	IFTM.pdf	130822 6770e73e5a6d57b66aced158990a512731 0397c	no	1

Warnings:

Information:

2	Fee Worksheet (SB06)	fee-info.pdf	30820 f1d4ae028653a0e362b34011f556a750edf c16ff	no	2
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Warnings:

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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.

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

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EXAMINER

VALENROD, YEVGENY

ART UNIT PAPER NUMBER

1672

DATE MAILED: 11/09/2016

Table with 5 columns: APPLICATION NO., FILING DATE, FIRST NAMED INVENTOR, ATTORNEY DOCKET NO., CONFIRMATION NO.
14/754,932 06/30/2015 Hitesh Batra 080618-1550 1865

TITLE OF INVENTION: PROCESS TO PREPARE TREPROSTINIL, THE ACTIVE INGREDIENT IN REMODULIN2

Table with 7 columns: APPLN. TYPE, ENTITY STATUS, ISSUE FEE DUE, PUBLICATION FEE DUE, PREV. PAID ISSUE FEE, TOTAL FEE(S) DUE, DATE DUE
nonprovisional UNDISCOUNTED \$960 50 50 \$960 02/09/2017

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:

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

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_____ (Signature)
_____ (Date)

APPLICATION NO: 14/754,932	FILING DATE 06/30/2015	FIRST NAMED INVENTOR Hitesh Batra	ATTORNEY DOCKET NO: 080618-1550	CONFIRMATION NO: 1865
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TITLE OF INVENTION: PROCESS TO PREPARE TREPROSTINIL, THE ACTIVE INGREDIENT IN REMODULIN2

APPLN. TYPE nonprovisional	ENTITY STATUS UNDISCOUNTED	ISSUE FEE DUE \$960	PUBLICATION FEE DUE \$0	PREV. PAID ISSUE FEE \$0	TOTAL FEE(S) DUE \$960	DATE DUE 02/09/2017
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EXAMINER VALENROD, YEVGENY	ART UNIT 1672	CLASS-SUBCLASS 562-466000
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1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

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- 3 _____

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

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

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- Applicant asserting small entity status. See 37 CFR 1.27
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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.

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14/754,932 06/30/2015 Hitesh Batra 080618-1550 1865

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EXAMINER

VALENROD, YEVGENY

ART UNIT PAPER NUMBER

1672

DATE MAILED: 11/09/2016

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.

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

Privacy Act Statement

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

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

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

Notice of Allowability	Application No. 14/754,932	Applicant(s) BATRA ET AL.	
	Examiner YEVGENY VALENROD	Art Unit 1672	AIA (First Inventor to File) Status No

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

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

1. This communication is responsive to reply filed on 10/25/16.
 A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on 7/19/16.
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 1,6 and 8-14. 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. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Examiner's Amendment/Comment |
| 2. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ | 6. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| 3. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 7. <input type="checkbox"/> Other _____. |
| 4. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. | |

/YEVGENY VALENROD/
Primary Examiner, Art Unit 1672

OK TO ENTER: /Y.V/

Atty. Dkt. No. 080618-1550
Appl. No. 14/754,932

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor Name: Hitesh BATRA
Title: AN IMPROVED PROCESS
TO PREPARE
TREPASTINIL, THE
ACTIVE INGREDIENT IN
REMODULIN®
Appl. No.: 14/754,932
Filing Date: 6/30/2015
Examiner: Yevgeny Valenrod
Art Unit: 1672
Confirmation Number: 1865


REQUEST FOR RECONSIDERATION

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

Commissioner:

This request is submitted in response to the outstanding final Office Action mailed on Oct. 19, 2016.


Remarks begin on page 2 of this document.

Issue Classification 	Application/Control No. 14754932	Applicant(s)/Patent Under Reexamination BATRA ET AL.
	Examiner YEVEGENY VALENROD	Art Unit 1672

CPC						
Symbol					Type	Version
C07C	59	/	72		F	2013-01-01
C07C	51	/	08		I	2013-01-01
C07C	51	/	412		I	2013-01-01
C07C	213	/	08		I	2013-01-01
C07C	51	/	41		I	2013-01-01
A01N	37	/	10		A	2013-01-01
C07C	39	/	12		A	2013-01-01
C07C	39	/	17		A	2013-01-01
C07C	59	/	60		A	2013-01-01
C07C	405	/	0075		I	2013-01-01
		/				
		/				
		/				
		/				


CPC Combination Sets								
Symbol					Type	Set	Ranking	Version
C07C	51	/	08		I	1	1	2013-01-01
C07C	59	/	72		I	1	2	2013-01-01
C07C	51	/	412		I	2	1	2013-01-01
C07C	59	/	72		I	2	2	2013-01-01

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	9	
YEVEGENY VALENROD/ Primary Examiner, Art Unit 1672	11/04/2016	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	none

Issue Classification 	Application/Control No. 14754932	Applicant(s)/Patent Under Reexamination BATRA ET AL.
	Examiner YEVEGENY VALENROD	Art Unit 1672


US ORIGINAL CLASSIFICATION					INTERNATIONAL CLASSIFICATION														
CLASS		SUBCLASS			CLAIMED					NON-CLAIMED									
562		468			C	0	7	C	59 : 72 (2006.01.01)										
CROSS REFERENCE(S)																			
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)																		

NONE		Total Claims Allowed:	
(Assistant Examiner) _____ (Date)		9	
YEVEGENY VALENROD/ Primary Examiner, Art Unit 1672		11/04/2016	
(Primary Examiner) _____ (Date)		O.G. Print Claim(s) 1	O.G. Print Figure none

Issue Classification 	Application/Control No. 14754932	Applicant(s)/Patent Under Reexamination BATRA ET AL.
	Examiner YEVEGENY VALENROD	Art Unit 1672

<input type="checkbox"/> Claims renumbered in the same order as presented by applicant		<input type="checkbox"/> CPA		<input checked="" type="checkbox"/> T.D.		<input type="checkbox"/> R.1.47									
Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
1	1														
2	6														
3	8														
4	9														
5	10														
6	11														
7	12														
8	13														
9	14														

NONE	(Assistant Examiner)	(Date)	Total Claims Allowed:	
			9	
YEVEGENY VALENROD/ Primary Examiner, Art Unit 1672		11/04/2016	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)		(Date)	1	none

Search Notes 	Application/Control No. 14754932	Applicant(s)/Patent Under Reexamination BATRA ET AL.
	Examiner YEVEGENY VALENROD	Art Unit 1672

CPC- SEARCHED		
Symbol	Date	Examiner
C07C 59/72; 51/08; 51/41; 51/412; 213/08; 405/0075	11/4/2016	YV

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
562	466	11/4/2016	YV

SEARCH NOTES		
Search Notes	Date	Examiner
EAST	10/14/2016	YV
Inventor	10/14/2016	YV
C07C 59/72; 51/08; 51/41; 51/412; 213/08; 405/0075	11/4/2016	YV

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner
C07C	59/72; 51/08; 51/41; 51/412; 213/08; 405/0075	11/4/2016	YV
562	466	11/4/2016	YV

	/YEVEGENY VALENROD/ Primary Examiner, Art Unit 1672
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Substitute for form 1449/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Application Number	14/754932
		Filing Date	6/30/2015
Date Submitted: October 21, 2016		First Named Inventor	Hitesh BATRA
		Art Unit	1672
(use as many sheets as necessary)		Examiner Name	Yevgeny Valenrod
		Attorney Docket Number	080618-1550
Sheet	1	of	1

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear

UNPUBLISHED U.S. PATENT APPLICATION DOCUMENTS					
Examiner Initials*	Cite No. ¹	U.S. Patent Application Document Serial Number-Kind Code ² (if known)	Filing Date of Cited Document MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document Country Code ³ -Number ⁴ - Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Documents	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	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 ⁶
	D1	Redacted Petitioner's Reply to Patent Owner's Response to Petition filed on September 27, 2016 in <i>Steadymed Ltd. (Petitioner), v. United Therapeutics Corporation (Patent Owner)</i> , Case IPR2016-00006, US Patent 8,497,393, with Exhibits 1022-1028.	

Examiner Signature	/YEVGENY VALENROD/	Date Considered	11/04/2016
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PTO/SB/08 (modified)

Substitute for form 1449/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Application Number	14/754932
Date Submitted: <u>FEB 29 2016</u>		Filing Date	6/30/2015
<i>(use as many sheets as necessary)</i>		First Named Inventor	Hitesh BATRA
Sheet	1	Art Unit	1672
	of 1	Examiner Name	Yevgeny Valenrod
		Attorney Docket Number	080618-1550

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	C1	2001/0038855 A1	11/08/2001	Desjardin et al.	
	C2	2001/0056095 A1	12/27/2001	Mylari	
	C3	4,434,164 A	02/28/1984	Lombardino	
	C4	5,466,713 A	11/14/1995	Blitstein-Willinger et al.	
	C5	5,506,265 A	04/09/1996	Blitstein-Willinger	
	C6	6,706,283 B1	03/16/2004	Appel et al.	


FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Documents	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
	C7	WO 98/18452 A1	05/07/1998	Shire Laboratories, Inc.		

NON PATENT LITERATURE DOCUMENTS						
Examiner Initials*	Cite No. ¹	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 ⁶
			C8	BIGHLEY et al., "Salt Forms of Drugs and Absorption," Encyclopedia of Pharmaceutical Technology, Swarbrick et al., Eds., 1995, 13:453-499.		
	C9	SIMONNEAU et al., "Continuous Subcutaneous Infusion of Treprostinil, a Prostacyclin Analogue, in Patients with Pulmonary Arterial Hypertension," Am. J. Respir. Crit. Care Med., 2002, 165:800-804.				

Examiner Signature	/YEVGENY VALENROD/	Date Considered	11/04/2016
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4818-3879-5054.1


ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /Y.V/

Index of Claims 	Application/Control No. 14754932	Applicant(s)/Patent Under Reexamination BATRA ET AL.
	Examiner YEVEGENY VALENROD	Art Unit 1672

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

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

CLAIM		DATE									
Final	Original	07/28/2015	09/10/2015	02/04/2016	10/14/2016	11/04/2016					
1	1	✓	=	✓	=	=					
	2	✓	=	✓	-	-					
	3	✓	=	✓	-	-					
	4	✓	-	-	-	-					
	5	✓	-	-	-	-					
2	6	✓	=	✓	=	=					
	7	✓	-	-	-	-					
3	8	✓	=	✓	=	=					
4	9			✓	=	=					
5	10			✓	=	=					
6	11			✓	=	=					
7	12			✓	=	=					
8	13			✓	✓	=					
9	14			✓	✓	=					

Application Number 	Application/Control No. 14/754,932	Applicant(s)/Patent under Reexamination BATRA ET AL.
Document Code - DISQ		Internal Document – DO NOT MAIL

TERMINAL DISCLAIMER	<input checked="" type="checkbox"/> APPROVED	<input type="checkbox"/> DISAPPROVED
Date Filed : 10/21/16	This patent is subject to a Terminal Disclaimer	

Approved/Disapproved by:
Felicia D. Roberts 8,242,305

U.S. Patent and Trademark Office

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor Name: Hitesh BATRA
Title: AN IMPROVED PROCESS
TO PREPARE
TREPASTINIL, THE
ACTIVE INGREDIENT IN
REMODULIN®
Appl. No.: 14/754,932
Filing Date: 6/30/2015
Examiner: Yevgeny Valenrod
Art Unit: 1672
Confirmation Number: 1865

REQUEST FOR RECONSIDERATION

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

Commissioner:

This request is submitted in response to the outstanding final Office Action mailed on Oct. 19, 2016.

Remarks begin on page 2 of this document.

REMARKS

Applicants respectfully request reconsideration and allowance of the present application.

Status of Claims

No amendments are presented.

Double Patenting

Claims 13-14 have been rejected for non-statutory double patenting as unpatentable over claims 24 and 26 of US Patent No. 8,242,305. Without acquiescing in the grounds of rejection and solely to expedite prosecution, Applicants submit a terminal disclaimer to overcome the rejection.

Concluding Remarks

Applicants believe that the application is in condition for allowance. Favorable reconsideration is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance prosecution.

The Commissioner is hereby authorized to charge any additional fees that may be required regarding this application under 37 C.F.R. §§ 1.16-1,17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing or a credit card payment form being unsigned, providing incorrect information resulting in a rejected credit card transaction, or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition

Atty. Dkt. No. 080618-1550
Appl. No. 14/754,932

for such extension under 37 C.F.R. § 1.136 and authorize payment of any such extension fees to
Deposit Account No. 19-0741.

Respectfully submitted,

Date Oct. 21, 2016

By /Stephen B. Maebius/

FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 672-5569
Facsimile: (202) 672-5399

Stephen B. Maebius
Attorney for Applicant
Registration No. 35,264

**TERMINAL DISCLAIMER TO OBTAIN A DOUBLE PATENTING
REJECTION OVER A "PRIOR" PATENT**Docket Number (Optional)
080618-1550

In re Application of: Hitesh BATRA, Sudersan M. TULADHAR, Raju PENMASTA and David A. WALSH

Application No.: 14/754932

Filed: 6/30/2015

For: AN IMPROVED PROCESS TO PREPARE TREPROSTINIL, THE ACTIVE INGREDIENT IN REMODULIN®

The applicant, United Therapeutics Corporation, owner of 100 percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of **prior patent** No. 8,242,305 as the term of said **prior patent** is presently shortened by any terminal disclaimer. The applicant hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the **prior patent** are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the applicant does not disclaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term of the **prior patent**, "as the term of said **prior patent** is presently shortened by any terminal disclaimer," in the event that said **prior patent** later;

- expires for failure to pay a maintenance fee;
- is held unenforceable;
- is found invalid by a court of competent jurisdiction;
- is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321;
- has all claims canceled by a reexamination certificate;
- is reissued; or
- is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

Check either box 1 or 2 below, if appropriate.

1. The undersigned is the applicant. If the applicant is an assignee, the undersigned is authorized to act on behalf of the assignee.

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

2. The undersigned is an attorney or agent of record. Reg. No. 35,264

/Stephen B. Maebius/
Signature

10/21/2015
Date

Stephen B. Maebius
Typed or printed name

Foley & Lardner LLP Attorney
Title

(202) 672-5569
Telephone Number

- Terminal disclaimer fee under 37 CFR 1.20(d) included.

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.

This collection of information is required by 37 CFR 1.321. 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.

Privacy Act Statement

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor Name: Hitesh BATRA
Title: AN IMPROVED PROCESS TO PREPARE
TREPROSTINIL, THE ACTIVE INGREDIENT IN
REMODULIN®
Application No.: 14/754932
Filing Date: 6/30/2015
Examiner: Yevgeny Valenrod
Art Unit: 1672
Confirmation No.: 1865

INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.56

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

Commissioner:

Applicant submits herewith documents for the Examiner's consideration in accordance with 37 CFR §§1.56, 1.97 and 1.98.

Applicant respectfully requests that each listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The submission of any document herewith is not an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document submitted herewith. However, in accordance with MPEP §

609.04(a)(I), Applicant hereby states that for items for which the date of publication supplied does not include the month of publication, the year of publication is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the particular month of publication is not in issue.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(d), before payment of the issue fee.

STATEMENT UNDER 37 CFR §1.97(e)

The undersigned hereby states in accordance with 37 CFR §1.97(e)(2) that no item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the undersigned, 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.

FEE

Fees in the amount of \$180.00 to cover the fee associated with an information disclosure statement are being paid by credit card via EFS-Web.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this submission under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account Number 19-0741.

Respectfully submitted,

Date October 21, 2016

By /Stephen B. Maebius/

FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 672-5569
Facsimile: (202) 672-5399

Stephen B. Maebius
Attorney for Applicant
Registration No. 35,264

Substitute for form 1449/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Application Number	14/754932
		Filing Date	6/30/2015
Date Submitted: October 21, 2016		First Named Inventor	Hitesh BATRA
		Art Unit	1672
(use as many sheets as necessary)		Examiner Name	Yevgeny Valenrod
		Attorney Docket Number	080618-1550
Sheet	1	of	1

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)				

UNPUBLISHED U.S. PATENT APPLICATION DOCUMENTS						
Examiner Initials*	Cite No. ¹	U.S. Patent Application Document		Filing Date of Cited Document MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Serial Number-Kind Code ² (if known)				

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. ¹	Foreign Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Documents	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³	Number ⁴ Kind Code ⁵ (if known)				

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	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 ⁶
	D1	Redacted Petitioner's Reply to Patent Owner's Response to Petition filed on September 27, 2016 in <i>Steadymed Ltd. (Petitioner), v. United Therapeutics Corporation (Patent Owner)</i> , Case IPR2016-00006, US Patent 8,497,393, with Exhibits 1022-1028.	

Examiner Signature		Date Considered	
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Electronic Patent Application Fee Transmittal

Application Number:	14754932			
Filing Date:	30-Jun-2015			
Title of Invention:	PROCESS TO PREPARE TREPROSTINIL, THE ACTIVE INGREDIENT IN REMODULIN2			
First Named Inventor/Applicant Name:	Hitesh Batra			
Filer:	Stephen Bradford Maebius/Karen Strawderman			
Attorney Docket Number:	080618-1550			
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:				
Submission- Information Disclosure Stmt	1806	1	180	180
STATUTORY OR TERMINAL DISCLAIMER	1814	1	160	160
Total in USD (\$)				340

Electronic Acknowledgement Receipt

EFS ID:	27282080
Application Number:	14754932
International Application Number:	
Confirmation Number:	1865
Title of Invention:	PROCESS TO PREPARE TREPROSTINIL, THE ACTIVE INGREDIENT IN REMODULIN2
First Named Inventor/Applicant Name:	Hitesh Batra
Customer Number:	22428
Filer:	Stephen Bradford Maebius/Karen Strawderman
Filer Authorized By:	Stephen Bradford Maebius
Attorney Docket Number:	080618-1550
Receipt Date:	21-OCT-2016
Filing Date:	30-JUN-2015
Time Stamp:	10:25:57
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	\$340
RAM confirmation Number	102116INTEFSW10264300
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		ReqReconsideration.pdf	106733 25da6ba13acc28671a094860fc9bed9d249 3ac0d4	yes	3
Multipart Description/PDF files in .zip description					
Document Description		Start	End		
Response After Final Action		1	1		
Applicant Arguments/Remarks Made in an Amendment		2	3		
Warnings:					
Information:					
2	Terminal Disclaimer Filed	TerminalDisclaimer.pdf	129824 1e79fccaf4496e82250a10bec1319150a801 09c5	no	2
Warnings:					
Information:					
3		IDS.pdf	169245 9f792501e7632ad007f811f68e125e7f65 ef50	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:					
4	Other Reference-Patent/App/Search documents	PetitionerReplyExhibits.pdf	13659957 807260443300ca31e002a07650997fde657 9751a	no	322
Warnings:					

Information:					
5	Fee Worksheet (SB06)	fee-info.pdf	32494	no	2
			April 10/11 15:45:02 10545984096129574091 1:09		
Warnings:					
Information:					
Total Files Size (in bytes):				14098253	
<p>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.</p> <p><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.</p> <p><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.</p> <p><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.</p>					



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www.uspto.gov

Table with 5 columns: APPLICATION NO., FILING DATE, FIRST NAMED INVENTOR, ATTORNEY DOCKET NO., CONFIRMATION NO. Includes application details for 14/754,932 and 22428, inventor Hitesh Batra, attorney Foley & Lardner LLP, examiner VALENROD, YEVGENY, art unit 1672, and notification date 10/19/2016.

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):

ipdocketing@foley.com

Office Action Summary	Application No. 14/754,932	Applicant(s) BATRA ET AL.	
	Examiner YEVGENY VALENROD	Art Unit 1672	AIA (First Inventor to File) Status No

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

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 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 8/11/16.
 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) 1,6 and 8-14 is/are pending in the application.
5a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 6) Claim(s) 1,6 and 8-12 is/are allowed.
- 7) Claim(s) 13-14 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/inft_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: _____

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

DETAILED ACTION

Rejection of claims 1-3, 6, 8 and 9 under 35 USC102(b) as anticipated by Moriarty et al is withdrawn in view applicants' arguments, amendments and the accompanying declarations.

Rejection of claims 10-12 under 35 USC 103(a) over Moriarty in view of Phares are withdrawn in view of applicants' arguments, amendments and the accompanying declarations

Maintained 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 claims at issue 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); and *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 a nonstatutory double patenting ground provided the reference application or patent either is shown to be commonly owned with this 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/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 <http://www.uspto.gov/patents/process/file/efs/guidance/eTD-info-l.jsp>.

Claims 13-14 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 24 and 26 of U.S. Patent No. 8,242,305 ('305). Although

the claims at issue are not identical, they are not patentably distinct from each other because:

Claim 24 of '305 is directed to a process for the preparation of compound IV (treprostinil). Said method comprises alkylation of benzindene triol to prepare compound (VI) followed by hydrolyzing compound (VI) and contacting the hydrolysis product with a base. In claim 26 the contacting base is diethanolamine.

Conclusion

Claims 1, 6, 8-14 are pending

Claims 1, 6, 8-12 are allowed

Claims 13-14 are rejected

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.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to YEVGENY VALENROD whose telephone number is (571)272-9049. The examiner can normally be reached on mon-fri 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fereydoun G. Sajjadi can be reached on 571-572-3311. 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.


/YEVGENY VALENROD/
Primary Examiner, Art Unit 1672

Index of Claims 	Application/Control No. 14754932	Applicant(s)/Patent Under Reexamination BATRA ET AL.
	Examiner YEVEGENY VALENROD	Art Unit 1672

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

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

CLAIM		DATE							
Final	Original	07/28/2015	09/10/2015	02/04/2016	10/14/2016				
	1	✓	=	✓	=				
	2	✓	=	✓	-				
	3	✓	=	✓	-				
	4	✓	-	-	-				
	5	✓	-	-	-				
	6	✓	=	✓	=				
	7	✓	-	-	-				
	8	✓	=	✓	=				
	9			✓	=				
	10			✓	=				
	11			✓	=				
	12			✓	=				
	13			✓	✓				
	14			✓	✓				

Search Notes 	Application/Control No. 14754932	Applicant(s)/Patent Under Reexamination BATRA ET AL.
	Examiner YEVEGENY VALENROD	Art Unit 1672

CPC- SEARCHED		
Symbol	Date	Examiner

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES		
Search Notes	Date	Examiner
EAST	10/14/2016	YV
Inventor	10/14/2016	YV

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner
C07C			

	/YEVEGENY VALENROD/ Primary Examiner, Art Unit 1672
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EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	1	("8497393").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2016/10/14 14:12
L2	1	("8242305").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2016/10/14 14:12
L3	1	("4683330").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2016/10/14 14:12
L4	1	("4306075").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2016/10/14 14:12
L5	32	((Hitesh) near2 (Batra)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2016/10/14 14:12
L6	24	((Sudersan) near2 (Tuladhar)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2016/10/14 14:12
L7	30	((Raju) near2 (Penmasta)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2016/10/14 14:12
L8	245	((David) near2 (Walsh)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2016/10/14 14:12
L9	273	L5 or L6 or L7 or L8	US-PGPUB; USPAT; USOCR	OR	ON	2016/10/14 14:12
L10	24	L9 and treprostinil	US-PGPUB; USPAT; USOCR	OR	ON	2016/10/14 14:12
L11	531	c07c59/72.cpc.	US-PGPUB; USPAT; USOCR	OR	ON	2016/10/14 14:12
L12	870	(562/466).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2016/10/14 14:12
L13	1274	L11 or L12	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2016/10/14 14:12
L14	44	L13 and treprostinil	US-PGPUB; USPAT; USOCR	OR	ON	2016/10/14 14:12

EAST Search History (Prior Art)

L15	40	L14 and purity	US-PGPUB; USPAT; USOCR	OR	ON	2016/10/14 14:12
L16	37	L15 and HPLC	US-PGPUB; USPAT; USOCR	OR	ON	2016/10/14 14:12
L17	1	("6765117").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2016/10/14 14:12
L18	2	wo "2005007081"	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2016/10/14 14:12
L19	2	"9242350"	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2016/10/14 14:12
L20	1	("8242305").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2016/10/14 14:12
L21	1	("9156786").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2016/10/14 14:12

EAST Search History (Interference)

< This search history is empty >						
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor Name: Hitesh BATRA
Title: AN IMPROVED PROCESS
TO PREPARE
TREPASTINIL, THE
ACTIVE INGREDIENT IN
REMODULIN®
Appl. No.: 14/754,932
Filing Date: 6/30/2015
Examiner: Yevgeny Valenrod
Art Unit: 1672
Confirmation Number: 1865

AMENDMENT & REQUEST FOR RECONSIDERATION

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

Commissioner:

This amendment is submitted in response to the outstanding, non-final Office Action mailed on February 11, 2016.

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

Remarks begin on page 4 of this document.

Amendments to the Claims:

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

Listing of Claims:

1. (Currently Amended) A pharmaceutical batch ~~comprising~~ consisting of treprostnil or a salt thereof and impurities resulting from ~~prepared by~~ (a) alkylating a benzindene triol, (b) hydrolyzing the product of step (a) to form a solution comprising treprostnil, (c) contacting the solution comprising treprostnil from step (b) with a base to form a salt of treprostnil, (d) isolating the salt of treprostnil, and (e) optionally reacting the salt of treprostnil with an acid to form treprostnil, and

 -wherein the pharmaceutical batch contains at least 2.9 g of treprostnil or its salt.

2.-5. (Canceled)

6. (Currently Amended) The pharmaceutical batch of claim 1, which has been dried under vacuum.

7. (Canceled)

8. (Currently Amended) A pharmaceutical product comprising a therapeutically effective amount of treprostnil from a pharmaceutical batch as claimed in claim 1.

9. (Currently Amended) A pharmaceutical product comprising a therapeutically effective amount of a salt of treprostnil from a pharmaceutical batch as claimed in claim 1.

10. (Currently Amended) The product of claim 9, wherein the salt is the diethanolamine salt of treprostnil.

11. (Currently Amended) A method of preparing a pharmaceutical product from a ~~high-purity~~ pharmaceutical batch as claimed in claim 1, comprising storing a pharmaceutical batch of a salt of treprostinil as claimed in claim 1 at ambient temperature, and preparing a pharmaceutical product from the pharmaceutical batch after storage.

12. (Previously Presented) A method as claimed in claim 11, wherein the salt of treprostinil is a diethanolamine salt.

13. (Currently Amended) A method of preparing a ~~high-purity~~ pharmaceutical batch as claimed in claim 1, comprising (a) alkylating a benzindene triol, (b) hydrolyzing the product of step (a) to form a solution comprising treprostinil, (c) contacting the solution comprising treprostinil from step (b) with a base to form a salt of treprostinil, (d) isolating the salt of treprostinil, and (e) optionally reacting the salt of treprostinil with an acid to form treprostinil.

14. (Previously Presented) A method as claimed in claim 13, wherein the salt of treprostinil is a diethanolamine salt.

REMARKS

Applicants respectfully request reconsideration and allowance of the present application.

Status of Claims

Applicants have amended claim 1 to recite a “pharmaceutical” batch, “consisting of” as the transitional phrase, and “impurities” resulting from the recited steps. Conforming amendments are made to claim 13 and dependent claims. Support for these amendments can be found in the Examples 4-6 of the specification. No new matter has been added. Claims 2 and 3 are canceled. Applicants reserve the right to file one or more continuing applications directed to any subject matter omitted by the present amendment.

After the amendment, claims 1, 6, and 8-14 are pending.

Interview

Applicants thank the Examiner for the courtesy of the interview held on July 22, 2016, during which the presently-presented amendments were discussed. Applicants have followed the Examiner’s suggestions for amendments and additionally address the points discussed at the Interview in the remarks below.

35 U.S.C. § 102

Claims 1-3, 6, 8, and 9 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Moriarty (2004). Applicants respectfully request reconsideration of the rejection.

Applicants filed a notification of related proceedings to bring to the Examiner’s attention documents from IPR2016-00006, which involves parent U.S. Patent No. 8,497,393. Certain information is redacted in those documents due to confidentiality. Documents provided in that notification include the Patent Owner’s Response and expert declarations from Dr. Williams and Ruffolo. These documents address the subject matter of the ’393 patent claims although certain information is relevant to the present claims as explained herein.

Claim 1 recites steps (a)-(e), which read on a commercial process used by the assignee of the present application. Prior to the current commercial process, the assignee used a process

based on Moriarty 2004. Because the assignee used both processes, the assignee had the opportunity to analyze the resulting products as reflected in certificates of analysis. In the IPR, Dr. Williams and Dr. Ruffolo used these certificates of analysis to explain that a pharmaceutical batch produced according to steps (a)-(e) of claim 1 is different from the product produced by the process described in Moriarty 2004. Williams Dec. at ¶¶94-99; Ruffolo Dec. at ¶¶66-72. Specifically, the processes result in products having different impurity profiles, and in fact, the pharmaceutical batch of claim 1 has higher average purity. Patent Owner's Response at Section III.C.

The differences are not merely academic, but critical to the successful manufacture of a clinical product. FDA uses both overall purity and levels of individual impurities ("purity specification") as a basis to regulate the manufacturing of pharmaceuticals. Batches that fall outside of the purity specification cannot be sold or used to treat patients. As noted in the Patent Owner's IPR Response, the differences between claim 1's pharmaceutical batch and a product produced according to the process of Moriarty were significant enough to result in FDA's acceptance of a new purity specification for the commercial product, thus proving that the products are not the same in the eyes of the FDA. Patent Owner's Response at Section III.C. Furthermore, this change constitutes a "major" change according to the classification system for manufacturing changes used by FDA. Ruffolo Dec. at ¶¶70-72. Clearly, the pharmaceutical batch of claim 1 differs from the product resulting from Moriarty's synthesis.

Accordingly, withdrawal of the rejection under 35 U.S.C. § 102(b) is requested.

35 U.S.C. § 103

Claims 10-12 stand rejected under 35 U.S.C. § 103(a) as obvious over Moriarty (2004) in view of Phares (WO 2005/007081 A2). Applicants respectfully request reconsideration of the rejection.

The rejection cites Phares for showing that it would have been obvious to form a diethanolamine salt using Moriarty's treprostinil. However, the differences in the resulting products, as explained above, would not have been expected based on the prior art. In particular, it would not have been obvious to use the salt formation step of Phares to decrease amounts of

stereoisomer impurities of treprostinil, which are acidic rather than neutral or basic. Williams Dec. at ¶102. When subject to salt-forming conditions, one of ordinary skill in the art would expect that any undesired stereoisomer of treprostinil would be included in the final salt product because the stereoisomer would also be converted to the corresponding salt under such salt-forming conditions. One of ordinary skill in the art would have had no reasonable expectation of success in removing any undesired treprostinil stereoisomer impurities by salt formation and subsequent regeneration of the free acid.

In addition, FDA's decision to adopt a new purity specification for the resulting product further establishes unobviousness of the presently claimed invention. Indeed, as noted above, the specification change is classified as a "major" change according to the FDA's classification system for manufacturing changes. See *Knoll Pharm. Co., Inc. v. Teva. Pharm. USA, Inc.*, 367 F.3d 1381, 1385 (Fed. Cir. 2004) (explaining that while FDA approval is not determinative of nonobviousness, it can be relevant in evaluating the objective indicia of nonobviousness). As noted in Dr. Ruffolo's Declaration, even small changes in impurity are important to FDA: "Regulatory agencies have also sought to increase levels of purity, and consequently decrease levels of impurities, in order to provide to the maximum extent possible, the highest level of safety to patients." Ruffolo Dec. at ¶36. This is due to the fact that even trace amounts of impurities can sometime pose serious health concerns.

Accordingly, withdrawal of the rejection under 35 U.S.C. § 103(a) is requested.

Double Patenting

Claims 13-14 have been rejected for non-statutory double patenting as unpatentable over claims 24 and 26 of US Patent No. 8,242,305. Applicants will address the rejection by filing a terminal disclaimer if still necessary after the above amendments upon confirming that the present claims are otherwise in condition for allowance.

Concluding Remarks

Applicants believe that the application is in condition for allowance. Favorable reconsideration is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance prosecution.

The Commissioner is hereby authorized to charge any additional fees that may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing or a credit card payment form being unsigned, providing incorrect information resulting in a rejected credit card transaction, or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. § 1.136 and authorize payment of any such extension fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date Aug. 11, 2016

By /Stephen B. Maebius/

FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 672-5569
Facsimile: (202) 672-5399

Stephen B. Maebius
Attorney for Applicant
Registration No. 35,264

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor Name: Hitesh BATRA
Title: AN IMPROVED PROCESS TO
PREPARE TREPROSTINIL,
THE ACTIVE INGREDIENT IN
REMODULIN®
Appl. No.: 14/754,932
Filing Date: 6/30/2015
Examiner: Yevgeny Valenrod
Art Unit: 1672
Confirmation Number: 1865

PETITION FOR EXTENSION OF TIME

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

Commissioner:

Applicant hereby petitions the Commissioner under 37 C.F.R. §1.136(a) for a three-month extension of time for response in the above-identified application for the period required to make the attached response timely.

The extension fee for response within the third month is \$1,400.00.

The above-identified fees of \$1,400.00 are being paid by credit card via EFS-Web.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to

Atty. Dkt. No 080618-1550

Deposit Account No. 19-0741.

Respectfully submitted,

Date Aug. 11, 2016

By /Stephen B. Maebius/

FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 672-5569
Facsimile: (202) 672-5399

Stephen B. Maebius
Attorney for Applicant
Registration No. 35,264

Electronic Patent Application Fee Transmittal

Application Number:	14754932			
Filing Date:	30-Jun-2015			
Title of Invention:	PROCESS TO PREPARE TREPROSTINIL, THE ACTIVE INGREDIENT IN REMODULIN2			
First Named Inventor/Applicant Name:	Hitesh Batra			
Filer:	Stephen Bradford Maebius/Mary Jo Boyce			
Attorney Docket Number:	080618-1550			
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 - 3 months with \$0 paid	1253	1	1400	1400
Miscellaneous:				
Total in USD (\$)				1400

Electronic Acknowledgement Receipt

EFS ID:	26612937
Application Number:	14754932
International Application Number:	
Confirmation Number:	1865
Title of Invention:	PROCESS TO PREPARE TREPROSTINIL, THE ACTIVE INGREDIENT IN REMODULIN2
First Named Inventor/Applicant Name:	Hitesh Batra
Customer Number:	22428
Filer:	Stephen Bradford Maebius/Mary Jo Boyce
Filer Authorized By:	Stephen Bradford Maebius
Attorney Docket Number:	080618-1550
Receipt Date:	11-AUG-2016
Filing Date:	30-JUN-2015
Time Stamp:	12:48:24
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	\$ 1400
RAM confirmation Number	12335
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		Response.pdf	139386 003f1e1f102cc971b1fb25a53f0b48a1314009bd	yes	7
Multipart Description/PDF files in .zip description					
		Document Description	Start	End	
		Amendment/Req. Reconsideration-After Non-Final Reject	1	1	
		Claims	2	3	
		Applicant Arguments/Remarks Made in an Amendment	4	7	
Warnings:					
Information:					
2	Extension of Time	Petition.pdf	96884 23a89f2e7ce897a352055a6686f677b9a53acda	no	2
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	31180 a31e4336058c8f5c1051a2e2e717717dccc90d69	no	2
Warnings:					
Information:					
Total Files Size (in bytes):			267450		

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.

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 14/754,932	Filing Date 06/30/2015	<input type="checkbox"/> To be Mailed.
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ENTITY: LARGE SMALL MICRO

APPLICATION AS FILED – PART I

FOR	NUMBER FILED	NUMBER EXTRA	RATE (\$)	FEE (\$)
<input type="checkbox"/> BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	
<input type="checkbox"/> SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A	N/A	
<input type="checkbox"/> EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	
TOTAL CLAIMS (37 CFR 1.16(l))	minus 20 =	*	X \$ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X \$ =	
<input type="checkbox"/> 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).			
<input type="checkbox"/> 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)	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)
AMENDMENT	08/11/2016	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR			
	Total (37 CFR 1.16(i))	+ 9	Minus ** 20	=	X \$ =	
	Independent (37 CFR 1.16(b))	+ 1	Minus *** 3	=	X \$ =	
	<input type="checkbox"/> Application Size Fee (37 CFR 1.16(s)) <input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))					
					TOTAL ADD'L FEE	

	(Column 1)	(Column 2)	(Column 3)	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR			
	Total (37 CFR 1.16(i))	+	Minus **	=	X \$ =	
	Independent (37 CFR 1.16(b))	+	Minus ***	=	X \$ =	
	<input type="checkbox"/> Application Size Fee (37 CFR 1.16(s)) <input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))					
					TOTAL ADD'L FEE	

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

LIE
TERRANCE LAWRENCE

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.



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

Table with 5 columns: APPLICATION NO., FILING DATE, FIRST NAMED INVENTOR, ATTORNEY DOCKET NO., CONFIRMATION NO. Includes application details for 14/754,932 and 22428, attorney information for Foley & Lardner LLP, examiner VALENROD, YEVGENY, art unit 1672, and notification date 07/27/2016.

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):

ipdocketing@foley.com

Applicant-Initiated Interview Summary	Application No. 14/754,932	Applicant(s) BATRA ET AL.	
	Examiner YEVGENY VALENROD	Art Unit 1672	

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

(1) YEVGENY VALENROD. (3) _____.

(2) Stephen Maebius. (4) _____.

Date of Interview: 22 July 2016.

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

Exhibit shown or demonstration conducted: Yes No.

If Yes, brief description: _____.

Issues Discussed 101 112 102 103 Others

(For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: 1.

Identification of prior art discussed: Moriarty et al.

Substance of Interview

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

A proposed amendment to Claim 1, wherein the phrase "batch comprising" would be replaced with the phrase "pharmaceutical batch consisting of" was discussed. Examiner expressed concern with the "consisting of language" excluding the impurities that are present in the product as a result of the preparatory steps. It was agreed that along with the reply Applicants will submit a declaration that would outline the difference in the impurities of the instant product compared with the product of Moriarty. In addition an amendment to claim 1 that would also generically include the process derived impurities into the "consisting of" grouping of product components. No agreement regarding patentability was reached.

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

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

Attachment

/YEVGENY VALENROD/
Primary Examiner, Art Unit 1672

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

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

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

37 CFR §1.2- Business to be transacted in writing.

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

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

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

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

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

The Form provides for recordation of the following information:

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

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

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

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

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

Examiner to Check for Accuracy

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

Substitute for form 1449/PTO		<i>Complete if Known</i>	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Application Number	14/754932
Date Submitted: <u>FEB 29 2016</u>		Filing Date	6/30/2015
<i>(use as many sheets as necessary)</i>		First Named Inventor	Hitesh BATRA
Sheet	1	of	1
		Art Unit	1672
		Examiner Name	Yevgeny Valenrod
		Attorney Docket Number	080618-1550

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	C1	2001/0038855 A1	11/08/2001	Desjardin et al.	
	C2	2001/0056095 A1	12/27/2001	Mylari	
	C3	4,434,164 A	02/28/1984	Lombardino	
	C4	5,466,713 A	11/14/1995	Blitstein-Willinger et al.	
	C5	5,506,265 A	04/09/1996	Blitstein-Willinger	
	C6	6,706,283 B1	03/16/2004	Appel et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Documents	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
	C7	WO 98/18452 A1	05/07/1998	Shire Laboratories, Inc.		

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	Cite No. ¹	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 ⁶
			C8	BIGHLEY et al., "Salt Forms of Drugs and Absorption," Encyclopedia of Pharmaceutical Technology, Swarbrick et al., Eds., 1995, 13:453-499.	
	C9	SIMONNEAU et al., "Continuous Subcutaneous Infusion of Treprostinil, a Prostacyclin Analogue, in Patients with Pulmonary Arterial Hypertension," Am. J. Respir. Crit. Care Med., 2002, 165:800-804.			

Examiner Signature		Date Considered	
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4818-3879-5054.1

Electronic Acknowledgement Receipt

EFS ID:	24949106
Application Number:	14754932
International Application Number:	
Confirmation Number:	1865
Title of Invention:	PROCESS TO PREPARE TREPROSTINIL, THE ACTIVE INGREDIENT IN REMODULIN2
First Named Inventor/Applicant Name:	Hitesh Batra
Customer Number:	22428
Filer:	Stephen Bradford Maebius/Karen Strawderman
Filer Authorized By:	Stephen Bradford Maebius
Attorney Docket Number:	080618-1550
Receipt Date:	18-FEB-2016
Filing Date:	30-JUN-2015
Time Stamp:	13:17:40
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Miscellaneous Incoming Letter	NtfRelatedProc.pdf	115520 <small>2c000976a9590001600100106d632ee1c 21</small>	no	2

Warnings:

Information:

2	Miscellaneous Incoming Letter	POPrelRspandExhibits.pdf	21312387 011b4b14fe07ac5811115aee066da702e65d6	no	975
Warnings:					
Information:					
Total Files Size (in bytes):			21427907		
<p>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.</p> <p><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.</p> <p><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.</p> <p><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.</p>					



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APPLICATION NO.	FILED DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/754,932	06/30/2015	Hitesh Batra	080618-1550	1865
22428	7890	02/11/2016	EXAMINER VALENROD, YEVGENY	
Foley & Lardner LLP 3000 K STREET N.W. SUITE 600 WASHINGTON, DC 20007-5109			ART UNIT	PAPER NUMBER
			1672	
			NOTIFICATION DATE	DELIVERY MODE
			02/11/2016	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):

ipdocketing@foley.com

Office Action Summary	Application No. 14/754,932	Applicant(s) BATRA ET AL.	
	Examiner YEVGENY VALENROD	Art Unit 1672	AIA (First Inventor to File) Status No

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

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 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 12/8/15.
 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) 1-3,6 and 8-14 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) 1-3,6 and 8-14 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/inft_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 12/8/15
- 3) Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 4) Other: _____

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

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 12/8/15 has been entered.

Claim Rejections - 35 USC § 102

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

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6, 8 and 9 are rejected under pre-AIA 35 U.S.C. 102(b) as being anticipated by Moriarty et al (Journal of Organic Chemistry, 2004, 69, 1890-1902).

Moriarty et al disclose a method for preparing treprostinil. Said method comprises the steps of: (a) alkylation of benzindene triol and (b) hydrolysis of the product of step (a) (page 1895, Scheme 4, compounds **34** to **35** to **7**; page 1902 preparation of compounds **35** and **7**). 441g of treprostinil (a therapeutically effective

amount) was prepared at 99.7% purity. Moriarty also discloses removing impurities via extraction and further purification via crystallization. Although the method of Moriarty and the steps recited in the instant claims are not identical, the product obtained is the same.

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same or obvious from the product of the prior art, the claim is unpatentable even though the prior art product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (MPEP § 2113).

Claim Rejections - 35 USC § 103

In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

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

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

said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under pre-AIA 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of pre-AIA 35 U.S.C. 103(c) and potential pre-AIA 35 U.S.C. 102(e), (f) or (g) prior art under pre-AIA 35 U.S.C. 103(a).

Claims 10-12 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Moriarty et al (Journal of Organic Chemistry, 2004, 69, 1890-1902) in view of Phares et al (WO 2005/007081 A2).

Scope of prior art

Moriarty et al disclose a method for preparing treprostinil. Said method comprises the steps of: (a) alkylation of benzindene triol and (b) hydrolysis of the product of step (a) (page 1895, Scheme 4, compounds **34** to **35** to **7**; page 1902 preparation of compounds **35** and **7**). 441g of treprostinil (compound 7) was prepared at 99.7% purity.

Ascertaining the difference

Moriarty fails to teach preparation of a diethanolamine salt of treprostinil.

Moriarty also fails to teach preparation of a pharmaceutical product comprising diethanolamine salt.

Secondary reference

Phares et al teach preparation of treprostinil diethanolamine by dissolving treprostinil acid and treating it with diethanolamine. Phares further discloses two polymorphs of treprostinil diethanolamine and discloses stability via their moisture sorption/desorption data (figure 22).

Obviousness

One skilled in the art practicing the invention of Phares would have found it obvious to prepare a diethanolamine salt of treprostinil prepared by the method of Moriarty. Moriarty discloses a method for preparing a treprostinil acid which is a needed starting material for the process of Phares. The resulting salt would meet the limitations directed to pharmaceutical product because treprostinil diethanolamine is the sole claimed component of the claimed pharmaceutical product.

One skilled in the art would have found it obvious to prepare a pharmaceutical product from the treprostinil diethanolamine salt of Phares prepared from the treprostinil free acid that has been obtained by the process of Moriarty. One would also find it obvious to store the treprostinil diethanolamine salt prior to preparation of a pharmaceutical composition. On page 88 Phares describes minimal weight loss at 5%RH. One would simply store the product in an anhydrous environment to avoid loss of product.

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 claims at issue 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); and *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 a nonstatutory double patenting ground provided the reference application or patent either is shown to be commonly owned with this 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/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 <http://www.uspto.gov/patents/process/file/efs/guidance/eTD-info-l.jsp>.

Claims 13-14 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 24 and 26 of U.S. Patent No. 8,242,305 ('305). Although the claims at issue are not identical, they are not patentably distinct from each other because:

Claim 24 of '305 is directed to a process for the preparation of compound IV (treprostinil). Said method comprises alkylation of benzindene triol to prepare compound (VI) followed by hydrolyzing compound (VI) and contacting the hydrolysis product with a base. In claim 26 the contacting base is diethanolamine.

Conclusion

Claims 1-3, 6, 8-14 are pending

Claims 1-3, 6, 8-14 are rejected

Any inquiry concerning this communication or earlier communications from the examiner should be directed to YEVGENY VALENROD whose telephone number is (571)272-9049. The examiner can normally be reached on mon-fri 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fereydoun G. Sajjadi can be reached on 571-572-3311. 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.

/YEVGENY VALENROD/
Primary Examiner, Art Unit 1672

Notice of References Cited	Application/Control No. 14/754,932	Applicant(s)/Patent Under Reexamination BATRA ET AL.	
	Examiner YEVGENY VALENROD	Art Unit 1672	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-8,242,305 B2	08-2012	Batra, Hitesh	C07C51/08	562/466
	B	US-				
	C	US-				
	D	US-				
	E	US-				
	F	US-				
	G	US-				
	H	US-				
	I	US-				
	J	US-				
	K	US-				
	L	US-				
	M	US-				


FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
	N	WO 2005007081 A2	01-2005	US	MOTTOLA DAVID	C07C59/70
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

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

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

Index of Claims 	Application/Control No. 14754932	Applicant(s)/Patent Under Reexamination BATRA ET AL.
	Examiner YEVEGENY VALENROD	Art Unit 1672

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

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

CLAIM		DATE							
Final	Original	07/28/2015	09/10/2015	02/04/2016					
1	1	✓	=	✓					
2	2	✓	=	✓					
3	3	✓	=	✓					
	4	✓	-	-					
	5	✓	-	-					
4	6	✓	=	✓					
	7	✓	-	-					
5	8	✓	=	✓					
	9			✓					
	10			✓					
	11			✓					
	12			✓					
	13			✓					
	14			✓					

Substitute for form 1449/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Application Number	14/754932
Date Submitted: <u>DEC 08 2015</u>		Filing Date	6/30/2015
(use as many sheets as necessary)		First Named Inventor	Hitesh BATRA
Sheet	1	Art Unit	1672
	of	Examiner Name	Yevgeny Valenrod
	1	Attorney Docket Number	080618-1550

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)				
	B1	3,703,544		11/21/1972	Morozowich	
	B2	3,888,916		06/10/1975	Sinkula	

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. ¹	Foreign Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Documents	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³	Number ⁴ Kind Code ⁵ (if known)				

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. ¹	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 ⁶
	B3	Steadymed Ltd., v. United Therapeutics Corporation, Petition for <i>Inter Partes</i> Review of U.S. Patent No. 8,497,393, under 37 CFR 42.100, dated October 1, 2015, with Exhibits 1009, 1010, 1017 and 1018.		
	B4	Ege, S., <i>Organic Chemistry Second Edition</i> , 1989, 541-547.		
	B5	Schoffstall et al., <i>Microscale and Miniscale Organic Chemistry Laboratory Experiments</i> , 2nd. Ed., 2004, 200-202.		
	B6	Wiberg, Kenneth, <i>Laboratory Technique in Organic Chemistry</i> , 1960, 112.		

Examiner Signature	/Yevgeny Valenrod/	Date Considered	02/04/2016
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EAST Search History (Prior Art)


Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	1	("8497393").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2016/02/04 14:02
L2	1	("8242305").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2016/02/04 14:02
L3	1	("4683330").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2016/02/04 14:02
L4	1	("4306075").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2016/02/04 14:02
L5	28	((Hitesh) near2 (Batra)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2016/02/04 14:02
L6	21	((Sudersan) near2 (Tuladhar)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2016/02/04 14:02
L7	29	((Raju) near2 (Penmasta)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2016/02/04 14:02
L8	235	((David) near2 (Walsh)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2016/02/04 14:02
L9	260	L5 or L6 or L7 or L8	US-PGPUB; USPAT; USOCR	OR	ON	2016/02/04 14:02
L10	23	L9 and treprostiniil	US-PGPUB; USPAT; USOCR	OR	ON	2016/02/04 14:02
L11	514	c07c59/72.cpc.	US-PGPUB; USPAT; USOCR	OR	ON	2016/02/04 14:02
L12	867	(562/466).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2016/02/04 14:02
L13	1255	L11 or L12	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2016/02/04 14:02
L14	39	L13 and treprostiniil	US-PGPUB; USPAT; USOCR	OR	ON	2016/02/04 14:02

EAST Search History (Prior Art)

L15	35	L14 and purity	US-PGPUB; USPAT; USOCR	OR	ON	2016/02/04 14:02
L16	33	L15 and HPLC	US-PGPUB; USPAT; USOCR	OR	ON	2016/02/04 14:02
L17	1	("6765117").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2016/02/04 14:03
L18	2	wo "2005007081"	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2016/02/04 15:34

EAST Search History (Interference)

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Search Notes 	Application/Control No. 14754932	Applicant(s)/Patent Under Reexamination BATRA ET AL.
	Examiner YEVEGENY VALENROD	Art Unit 1672

CPC- SEARCHED		
Symbol	Date	Examiner

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES		
Search Notes	Date	Examiner
EAST	2/4/2016	YV
Inventor	2/4/2016	YV

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner
C07C			

	/YEVEGENY VALENROD/ Primary Examiner, Art Unit 1672
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor Name: Hitesh BATRA
Title: AN IMPROVED PROCESS TO PREPARE
TREPASTINIL, THE ACTIVE INGREDIENT IN
REMODULIN®
Appl. No.: 14/754932
Appl. Filing Date: 6/30/2015
Examiner: Yevgeny Valenrod
Art Unit: 1672
Confirmation Number: 1865

**REQUEST FOR CONTINUED EXAMINATION (RCE)
TRANSMITTAL**

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

Commissioner:

This is a Request for Continued Examination (RCE) under 37 C.F.R. § 1.114 of the above-identified application. This RCE and the enclosed items listed below are being filed prior to the earliest of: (1) payment of the issue fee (unless a petition under 37 C.F.R. § 1.313 is granted); (2) abandonment of the application; or (3) the filing of a notice of appeal to the U.S. Court of Appeals for the Federal Circuit under 35 U.S.C. §141, or the commencement of a civil action under 35 U.S.C. §145 or §146 (unless the appeal or civil action is terminated).

1. Submission required under 37 C.F.R. §1.114: (check items that apply)

a. Previously submitted:

- Please enter and consider the amendment and/or reply previously filed on ___.
- Please consider the Affidavit(s)/Declaration(s) previously filed on ___ but not considered.
- Please consider the arguments in the Appeal Brief or Reply previously filed on ___.
- Other Documents

b. Enclosed are:

- Amendment/Reply.
- Affidavit(s)/Declaration(s).
- Information Disclosure Statement, Form PTO/SB/08 and listed references.
- PTO/SB/424 - Request for Prioritized Examination.
- Other Documents

Miscellaneous:

- Suspension of action of the above-identified application is requested under 37 C.F.R. § 1.103(c) for a period of ___ months.

The filing fee is calculated below at the large entity rate:

	Claims as Amended	Previously Paid For	Extra Claims Present	Rate	Fee Totals
RCE Fee 1.17(e):				\$1,200.00	= \$1,200.00
				0	
Total Claims:	11	- 20	= 0	x \$80.00	= \$0.00
Independents	1	- 3	= 0	x \$420.00	= \$0.00
First presentation of any Multiple Dependent Claims:				+ \$780.00	= \$0.00
CLAIMS FEE TOTAL:					= \$1,200.00

Applicant hereby petitions for an extension of time under 37 C.F.R. §1.136(a) for the total number of months checked below:

<input type="checkbox"/>	Extension for response filed within the first month:	\$200.00	0	\$0.00
<input type="checkbox"/>	Extension for response filed within the second month:	\$600.00		\$0.00
<input type="checkbox"/>	Extension for response filed within the third month:	\$1,400.00		\$0.00
<input type="checkbox"/>	Extension for response filed within the fourth month:	\$2,200.00		\$0.00
<input type="checkbox"/>	Extension for response filed within the fifth month:	\$3,000.00		\$0.00
	EXTENSION FEE SUBTOTAL:			\$0.00
	EXTENSION FEE ALREADY PAID:	-		\$0.00
	EXTENSION FEE TOTAL			\$0.00
	CLAIMS AND EXTENSION FEE TOTAL:			\$1,200.00
	Prioritized Examination fee (Track I) under 37 C.F.R. § 1.17 (e)			\$0.00
	Processing Fee (Track I) under 37 C.F.R. § 1.17 (i)			\$0.00
	Publication Fee			\$0.00
<input type="checkbox"/>	Suspension of action requested under 37 C.F.R. § 1.103(c)			\$0.00
	TOTAL FEE:			\$1,200.00

The above-identified fees of \$1,200.00 are being paid by credit card via EFS-Web.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Please direct all correspondence to the undersigned attorney or agent at the address indicated below.

Respectfully submitted,

Date DEC 08 2015

FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 672-5569
Facsimile: (202) 672-5399

By 

Stephen B. Maebius
Attorney for Applicant
Registration No. 35,264

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor Name: Hitesh BATRA
Title: AN IMPROVED PROCESS
TO PREPARE
TREPASTINIL, THE
ACTIVE INGREDIENT IN
REMODULIN®
Appl. No.: 14/754,932
Filing Date: 6/30/2015
Examiner: Yevgeny Valenrod
Art Unit: 1672
Confirmation Number: 1865

AMENDMENT ACCOMPANYING RCE

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

Commissioner:

This amendment is submitted together with an RCE following receipt of a Notice of Allowability mailed on Sept. 18, 2015.

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

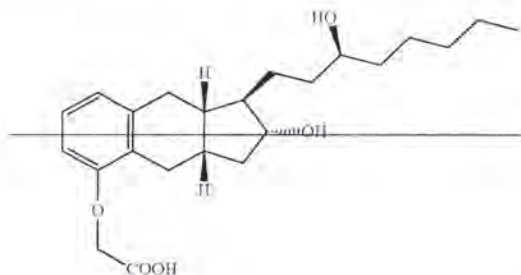
Remarks begin on page 4 of this document.

Amendments to the Claims:

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

Listing of Claims:

1. (Currently Amended) A high-purity treprostinil batch comprising treprostinil or a salt thereof prepared by (a) alkylating a benzindene triol, (b) hydrolyzing the product of step (a) to form a solution comprising treprostinil, (c) contacting the solution comprising treprostinil from step (b) with a base to form a salt of treprostinil, (d) isolating the salt of treprostinil, and (e) optionally reacting the salt of treprostinil with an acid to form treprostinil, and wherein purity of treprostinil in the batch is at least 99.8% as determined by HPLC and the treprostinil in the batch has the formula:



, wherein the batch contains at least 2.9 g of treprostinil or its salt.

2. (Currently Amended) The high-purity treprostinil batch of claim 1, wherein purity of treprostinil or its salt in the batch is at least 99.9% 99.0% as determined by HPLC.
3. (Currently Amended) The high-purity treprostinil batch of claim 1, wherein the batch does not contain impurities resulting from said alkylation or hydrolysis of an intermediate.
- 4-5. (Canceled)
6. (Currently Amended) The high-purity treprostinil batch of claim 1, which has been dried under vacuum.
7. (Canceled)
8. (Currently Amended) A pharmaceutical product comprising a therapeutically effective amount of treprostinil from a high-purity treprostinil batch as claimed in claim 1.

9. (New) A pharmaceutical product comprising a therapeutically effective amount of a salt of treprostnil from a batch as claimed in claim 1.
10. (New) The product of claim 9 wherein the salt is the diethanolamine salt of treprostnil.
11. (New) A method of preparing a pharmaceutical product from a high purity batch as claimed in claim 1, comprising storing a batch of a salt of treprostnil as claimed in claim 1 at ambient temperature, and preparing a pharmaceutical product from the batch after storage.
12. (New) A method as claimed in claim 11, wherein the salt of treprostnil is a diethanolamine salt.
13. (New) A method of preparing a high purity batch as claimed in claim 1, comprising (a) alkylating a benzindene triol, (b) hydrolyzing the product of step (a) to form a solution comprising treprostnil, (c) contacting the solution comprising treprostnil from step (b) with a base to form a salt of treprostnil, (d) isolating the salt of treprostnil, and (e) optionally reacting the salt of treprostnil with an acid to form treprostnil.
14. (New) A method as claimed in claim 13, wherein the salt of treprostnil is a diethanolamine salt.

PRELIMINARY REMARKS

Applicants respectfully request reconsideration and allowance of the present application.

Status of Claims

Applicants have amended claim 1 without prejudice or disclaimer. Applicants have added dependent method claims 9-14, support for which can be found in the original claims and in paragraph 46. Support for the amended claim 1 may be found throughout the specification as filed, including paragraphs 30-31. No new matter has been added. Applicants reserve the right to file one or more continuing application directed to the subject matter omitted by the present amendment.

After the amendment, claims 1-3, 6, and 8-14 are pending. The above claims should be allowable for reasons set forth in prior responses.

Concluding Remarks

Applicants believe that the application is in condition for allowance. Favorable reconsideration is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance prosecution.

The Commissioner is hereby authorized to charge any additional fees that may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing or a credit card payment form being unsigned, providing incorrect information resulting in a rejected credit card transaction, or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions

Atty. Dkt. No. 080618-1550
Appl. No. 14/754,932

for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extension fees to
Deposit Account No. 19-0741.

Respectfully submitted,

Date DEC 08 2015

By



FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 672-5569
Facsimile: (202) 672-5399

Stephen B. Maebius
Attorney for Applicant
Registration No. 35,264

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor Name: Hitesh BATRA
Title: AN IMPROVED PROCESS TO PREPARE
TREPROSTINIL, THE ACTIVE INGREDIENT IN
REMODULIN®
Appl. No.: 14/754932
Filing Date: 6/30/2015
Examiner: Yevgeny Valenrod
Art Unit: 1672
Confirmation Number: 1865

INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.56

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

Commissioner:

Applicant submits herewith documents for the Examiner's consideration in accordance with 37 CFR §§1.56, 1.97 and 1.98.

Applicant respectfully requests that each listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The submission of any document herewith is not an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any

rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document submitted herewith.

CONCISE EXPLANATION OF RELEVANCE

Document B3 is a Petition for *Inter Partes* Review filed against parent patent U.S. 8,497,393, dated October 1, 2015, including Exhibits 1009, 1010, 1017 and 1018. Documents B1-B2 and B4-B6 are exhibits from said IPR Petition which are prior art items not already of record in the present application.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), after an RCE and before the first Office Action on the merits.

It is believed no fees are due for the present IDS. The Commissioner is hereby authorized to charge any additional fees which may be required regarding this submission under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Date DEC 08 2015

By 

FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 672-5569
Facsimile: (202) 672-5399

Stephen B. Maebius
Attorney for Applicant
Registration No. 35,264

Substitute for form 1449/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Application Number	14/754932
Date Submitted: <u>DEC 08 2015</u>		Filing Date	6/30/2015
(use as many sheets as necessary)		First Named Inventor	Hitesh BATRA
Sheet	1	Art Unit	1672
	of	Examiner Name	Yevgeny Valenrod
	1	Attorney Docket Number	080618-1550

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)				
	B1	3,703,544		11/21/1972	Morozowich	
	B2	3,888,916		06/10/1975	Sinkula	

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. ¹	Foreign Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Documents	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ - Kind Code ⁵ (if known)					

NON PATENT LITERATURE DOCUMENTS						
Examiner Initials*	Cite No. ¹	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 ⁶
			B3	Steadymed Ltd., v. United Therapeutics Corporation, Petition for <i>Inter Partes</i> Review of U.S. Patent No. 8,497,393, under 37 CFR 42.100, dated October 1, 2015, with Exhibits 1009, 1010, 1017 and 1018.		
	B4	Ege, S., <i>Organic Chemistry Second Edition</i> , 1989, 541-547.				
	B5	Schoffstall et al., <i>Microscale and Miniscale Organic Chemistry Laboratory Experiments</i> , 2nd. Ed., 2004, 200-202.				
	B6	Wiberg, Kenneth, <i>Laboratory Technique in Organic Chemistry</i> , 1960, 112.				

Examiner Signature		Date Considered	
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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 NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
14/754,932	06/30/2015	Hitesh Batra	080618-1550

CONFIRMATION NO. 1865

22428
Foley & Lardner LLP
3000 K STREET N.W.
SUITE 600
WASHINGTON, DC 20007-5109

PUBLICATION NOTICE



Title:PROCESS TO PREPARE TREPROSTINIL, THE ACTIVE INGREDIENT IN REMODULIN2

Publication No.US-2015-0299091-A1

Publication Date:10/22/2015

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 Office of Public Records. The Office of Public Records can be reached by telephone at (703) 308-9726 or (800) 972-6382, by facsimile at (703) 305-8759, by mail addressed to the United States Patent and Trademark Office, Office of Public Records, 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 <http://pair.uspto.gov/>. 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 Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101



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UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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NOTICE OF ALLOWANCE AND FEE(S) DUE

22428 7590 09/18/2015
Foley & Lardner LLP
3000 K STREET N.W.
SUITE 600
WASHINGTON, DC 20007-5109

EXAMINER

VALENROD, YEVGENY

ART UNIT PAPER NUMBER

1672

DATE MAILED: 09/18/2015

Table with 5 columns: APPLICATION NO., FILING DATE, FIRST NAMED INVENTOR, ATTORNEY DOCKET NO., CONFIRMATION NO.
14/754,932 06/30/2015 Hitesh Batra 080618-1550 1865

TITLE OF INVENTION: PROCESS TO PREPARE TREPROSTINIL, THE ACTIVE INGREDIENT IN REMODULIN2

Table with 7 columns: APPLN. TYPE, ENTITY STATUS, ISSUE FEE DUE, PUBLICATION FEE DUE, PREV. PAID ISSUE FEE, TOTAL, FEE(S) DUE, DATE DUE
nonprovisional UNDISCOUNTED \$960 50 50 \$960 12/18/2015

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

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

HOW TO REPLY TO THIS NOTICE:

- I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.
If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.
If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".
For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

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

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

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

PART B - FEE(S) TRANSMITTAL

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

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

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

22428 7590 09/18/2015
Foley & Lardner LLP
3000 K STREET N.W.
SUITE 600
WASHINGTON, DC 20007-5109

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

Certificate of Mailing or Transmission

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

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

APPLICATION NO: 14/754,932	FILING DATE 06/30/2015	FIRST NAMED INVENTOR Hitesh Batra	ATTORNEY DOCKET NO: 080618-1550	CONFIRMATION NO: 1865
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TITLE OF INVENTION: PROCESS TO PREPARE TREPROSTINIL, THE ACTIVE INGREDIENT IN REMODULIN2

APPLN. TYPE nonprovisional	ENTITY STATUS UNDISCOUNTED	ISSUE FEE DUE \$960	PUBLICATION FEE DUE \$0	PREV. PAID ISSUE FEE \$0	TOTAL FEE(S) DUE \$960	DATE DUE 12/18/2015
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EXAMINER VALENROD, YEVGENY	ART UNIT 1672	CLASS-SUBCLASS 562-466000
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1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
 Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
 "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a **Customer Number** is required.

2. For printing on the patent front page, list
 (1) The names of up to 3 registered patent attorneys or agents OR, alternatively, 1 _____
 (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. 2 _____
 3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)
 PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.
 (A) NAME OF ASSIGNEE _____ (B) RESIDENCE: (CITY and STATE OR COUNTRY) _____

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

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

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

5. Change in Entity Status (from status indicated above)
 Applicant certifying micro entity status. See 37 CFR 1.29
 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. _____



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Table with 5 columns: APPLICATION NO., FILING DATE, FIRST NAMED INVENTOR, ATTORNEY DOCKET NO., CONFIRMATION NO.
14/754,932 06/30/2015 Hitesh Batra 080618-1550 1865

22428 7590 09/18/2015
Foley & Lardner LLP
3000 K STREET N.W.
SUITE 600
WASHINGTON, DC 20007-5109

Table with 1 column: EXAMINER

VALENROD, YEVGENY

Table with 2 columns: ART UNIT, PAPER NUMBER

1672

DATE MAILED: 09/18/2015

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

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

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

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

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

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

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

Privacy Act Statement

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

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

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

Notice of Allowability	Application No. 14/754,932	Applicant(s) BATRA ET AL.	
	Examiner YEVGENY VALENROD	Art Unit 1672	AIA (First Inventor to File) Status No

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

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

1. This communication is responsive to reply filed on 9/1/15.
 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 1-3, 6, 8. 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. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Examiner's Amendment/Comment |
| 2. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ | 6. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| 3. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 7. <input type="checkbox"/> Other _____. |
| 4. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____ | |

/YEVGENY VALENROD/
Primary Examiner, Art Unit 1672

Search Notes 	Application/Control No. 14754932	Applicant(s)/Patent Under Reexamination BATRA ET AL.
	Examiner YEVEGENY VALENROD	Art Unit 1672

CPC- SEARCHED		
Symbol	Date	Examiner


CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES		
Search Notes	Date	Examiner
		YV
EAST	9/10/2015	YV
Inventor	9/10/2015	YV

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner
C07C	59/72	9/10/2015	YV
562	466	9/10/2015	YV

	/YEVEGENY VALENROD/ Primary Examiner, Art Unit 1672
--	--

Issue Classification 	Application/Control No. 14754932	Applicant(s)/Patent Under Reexamination BATRA ET AL.
	Examiner YEVEGENY VALENROD	Art Unit 1672

<input type="checkbox"/> Claims renumbered in the same order as presented by applicant		<input type="checkbox"/> CPA		<input checked="" type="checkbox"/> T.D.		<input type="checkbox"/> R.1.47									
Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
1	1														
2	2														
3	3														
4	6														
5	8														

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	5	
YEVEGENY VALENROD/ Primary Examiner, Art Unit 1672	09/10/2015	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	none

EAST Search History (Prior Art)


Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	1	("8497393").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2015/09/10 15:36
L2	1	("8242305").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2015/09/10 15:36
L3	1	("4683330").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2015/09/10 15:36
L4	1	("4306075").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2015/09/10 15:36
L5	23	((Hitesh) near2 (Batra)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2015/09/10 15:36
L6	17	((Sudersan) near2 (Tuladhar)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2015/09/10 15:36
L7	26	((Raju) near2 (Penmasta)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2015/09/10 15:36
L8	230	((David) near2 (Walsh)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2015/09/10 15:36
L9	253	L5 or L6 or L7 or L8	US-PGPUB; USPAT; USOCR	OR	ON	2015/09/10 15:36
L10	19	L9 and treprostinil	US-PGPUB; USPAT; USOCR	OR	ON	2015/09/10 15:36
L11	498	c07c59/72.cpc.	US-PGPUB; USPAT; USOCR	OR	ON	2015/09/10 15:36
L12	858	(562/466).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2015/09/10 15:36
L13	1236	L11 or L12	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/09/10 15:36
L14	32	L13 and treprostinil	US-PGPUB; USPAT; USOCR	OR	ON	2015/09/10 15:36

EAST Search History (Prior Art)

L15	29	L14 and purity	US-PGPUB; USPAT; USOCR	OR	ON	2015/09/10 15:36
L16	27	L15 and HPLC	US-PGPUB; USPAT; USOCR	OR	ON	2015/09/10 15:36


EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L17	0	(562/466).CCLS.	UPAD	OR	OFF	2015/09/10 15:36
L18	0	c07c59/72.cpc.	UPAD	OR	ON	2015/09/10 15:36

Index of Claims 	Application/Control No. 14754932	Applicant(s)/Patent Under Reexamination BATRA ET AL.
	Examiner YEVEGENY VALENROD	Art Unit 1672

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

<input type="checkbox"/> Claims renumbered in the same order as presented by applicant		<input type="checkbox"/> CPA		<input checked="" type="checkbox"/> T.D.		<input type="checkbox"/> R.1.47			
CLAIM		DATE							
Final	Original	07/28/2015	09/10/2015						
1	1	✓	=						
2	2	✓	=						
3	3	✓	=						
	4	✓	-						
	5	✓	-						
4	6	✓	=						
	7	✓	-						
5	8	✓	=						

Application Number 	Application/Control No. 14/754,932	Applicant(s)/Patent under Reexamination BATRA ET AL.
Document Code - DISQ		Internal Document – DO NOT MAIL

TERMINAL DISCLAIMER	<input checked="" type="checkbox"/> APPROVED	<input type="checkbox"/> DISAPPROVED
Date Filed : 9/1/15	This patent is subject to a Terminal Disclaimer	

Approved/Disapproved by:

Felicia D. Roberts

8,497,393

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.

**TERMINAL DISCLAIMER TO OBTAIN A DOUBLE PATENTING
REJECTION OVER A "PRIOR" PATENT**Docket Number (Optional)
080618-1550

In re Application of: Hitesh BATRA, Sudersan M. TULADHAR, Raju PENMASTA and David A. WALSH

Application No.: 14/754932

Filed: 6/30/2015

For: AN IMPROVED PROCESS TO PREPARE TREPROSTINIL, THE ACTIVE INGREDIENT IN REMODULIN®

The applicant, United Therapeutics Corporation, owner of 100 percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of **prior patent** No. 8,497,393 as the term of said **prior patent** is presently shortened by any terminal disclaimer. The applicant hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the **prior patent** are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the applicant does not disclaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term of the **prior patent**, "as the term of said **prior patent** is presently shortened by any terminal disclaimer," in the event that said **prior patent** later:

- expires for failure to pay a maintenance fee;
- is held unenforceable;
- is found invalid by a court of competent jurisdiction;
- is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321;
- has all claims canceled by a reexamination certificate;
- is reissued; or
- is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

Check either box 1 or 2 below, if appropriate.

1. The undersigned is the applicant. If the applicant is an assignee, the undersigned is authorized to act on behalf of the assignee.

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

2. The undersigned is an attorney or agent of record. Reg. No. 35,264

/Stephen B. Maebius/
Signature

9/1/2015
Date

Stephen B. Maebius
Typed or printed name

Foley & Lardner LLP Attorney
Title

(202) 672-5569
Telephone Number

- Terminal disclaimer fee under 37 CFR 1.20(d) included.

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.

This collection of information is required by 37 CFR 1.321. 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.

Privacy Act Statement

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

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

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

Electronic Patent Application Fee Transmittal

Application Number:	14754932			
Filing Date:	30-Jun-2015			
Title of Invention:	PROCESS TO PREPARE TREPROSTINIL, THE ACTIVE INGREDIENT IN REMODULIN®			
First Named Inventor/Applicant Name:	Hitesh Batra			
Filer:	Stephen Bradford Maebius/annamarie dubossi			
Attorney Docket Number:	080618-1550			
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:				
Statutory or Terminal Disclaimer	1814	1	160	160

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Extension-of-Time:				
Miscellaneous:				
Total in USD (\$)				160

Electronic Acknowledgement Receipt

EFS ID:	23368581
Application Number:	14754932
International Application Number:	
Confirmation Number:	1865
Title of Invention:	PROCESS TO PREPARE TREPROSTINIL, THE ACTIVE INGREDIENT IN REMODULIN®
First Named Inventor/Applicant Name:	Hitesh Batra
Customer Number:	22428
Filer:	Stephen Bradford Maebius/annamarie dubossi
Filer Authorized By:	Stephen Bradford Maebius
Attorney Docket Number:	080618-1550
Receipt Date:	01-SEP-2015
Filing Date:	30-JUN-2015
Time Stamp:	13:06:40
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	\$ 160
RAM confirmation Number	10517
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	Amendment/Req. Reconsideration-After Non-Final Reject.	080618-1550_RespNon_FinalAmend_Reply.pdf	116090 aa23a47a81705799f17e20718b9008bd9e257ca	no	5

Warnings:

Information:

2	Terminal Disclaimer Filed	080618-1550_Terminal_Disclaimer_over_USP_8497393.pdf	131753 758cd6264d96a88f1a8e97c15b932f1130903	no	2
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Warnings:

Information:

3	Fee Worksheet (SB06)	fee-info.pdf	31020 2b545d220b5704a3b0aa515aed69c708f9702	no	2
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Warnings:

Information:

Total Files Size (in bytes): 278863

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.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor Name: Hitesh BATRA
Title: AN IMPROVED PROCESS
TO PREPARE
TREPASTINIL, THE
ACTIVE INGREDIENT IN
REMODULIN®
Appl. No.: 14/754,932
Filing Date: 6/30/2015
Examiner: Yevgeny Valenrod
Art Unit: 1672
Confirmation Number: 1865

AMENDMENT AND REPLY UNDER 37 CFR § 1.111

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

Commissioner:

This paper responds to the outstanding non-final Office Action dated August 3, 2015, and a telephonic interview conducted on August 4, 2015, by Applicants' representative, Alexey Saprigin (Reg. # 56,439), with Examiner Yevgeny Valenrod.

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

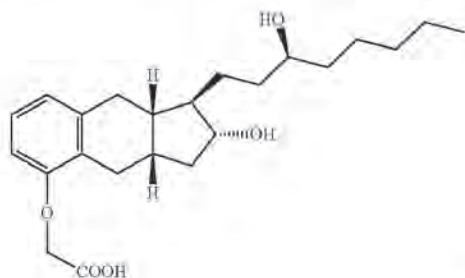
Remarks begin on page 3 of this document.

Amendments to the Claims:

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

Listing of Claims:

1. (Currently Amended) A high purity treprostnil batch, wherein purity of treprostnil in the batch is at least 99.8% as determined by HPLC and the treprostnil in the batch has the formula:



, wherein the batch contains at least 2.9 g of

treprostnil.

2. (Original) The high purity treprostnil batch of claim 1, wherein purity of treprostnil in the batch is at least 99.9% as determined by HPLC.
3. (Original) The high purity treprostnil batch of claim 1, wherein the batch does not contain impurities resulting from alkylation or hydrolysis of an intermediate.
- 4-5. (Canceled)
6. (Original) The high purity treprostnil batch of claim 1, which has been dried under vacuum.
7. (Canceled)
8. (Original) A pharmaceutical product comprising a therapeutically effective amount of treprostnil from a high purity treprostnil batch as claimed in claim 1.

REMARKS

Applicants respectfully request reconsideration and allowance of the present application.

Status of Claims

Applicants have canceled claims 4, 5 and 7, without prejudice or disclaimer. Applicants reserve the right to file one or more continuing application directed to the canceled subject matter.

Applicants have amended claim 1, without prejudice or disclaimer. Applicants reserve the right to file one or more continuing application directed to the subject matter omitted by the present amendment. Support for the amended claim 1 may be found throughout the specification as filed, including examined claim 4. No new matter has been added.

After the amendment, claims 1-3, 5-6 and 8 are pending.

August 4th interview

Applicants thank the Examiner for the interview, during which Applicants discussed options for addressing indefiniteness and anticipation rejections. The subject matter of the interview may be gleaned from this response.

Rejections under 35 USC § 112, ¶ 2

Claims 1, 2, 3, 6, 7 and 8 stand rejected as indefinite. Applicants believe that the revised claim set obviates the rejections. Accordingly, Applicants request withdrawal of the rejection.

Rejections under 35 USC § 102(b)

Claims 1, 2, 3, 6, 7 and 8 stand rejected as anticipated by Moriarty et al. (J. Org. Chem. 2004, 69(6), 1890-1902). Applicants believe that the revised claim set obviates the rejection because amended claim 1 contains all the elements of examined claim 4, which is not subject to the present anticipation rejection over Moriarty. Accordingly, Applicants request withdrawal of the rejection.

Double patenting rejections

Claims 1-8 stand rejected as unpatentable over claims 9 and 15 and U.S. patent no. 8,497,393 (the '393 patent). Although Applicants disagree with the rejection, Applicants believe that the enclosed terminal disclaimer over the '393 patent obviates the rejection. Accordingly, Applicants request withdrawal of the rejection.

Concluding Remarks

Applicants believe that the application is in condition for allowance. Favorable reconsideration is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance prosecution.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing or a credit card payment form being unsigned, providing incorrect information resulting in a rejected credit card transaction, or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extension fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date Sept. 1, 2015

By /Stephen B. Maebius/

FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 672-5569
Facsimile: (202) 672-5399

Stephen B. Maebius
Attorney for Applicant
Registration No. 35,264

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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 14/754,932	Filing Date 06/30/2015	<input type="checkbox"/> To be Mailed.
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ENTITY: LARGE SMALL MICRO

APPLICATION AS FILED – PART I

FOR	NUMBER FILED	NUMBER EXTRA	RATE (\$)	FEE (\$)
<input type="checkbox"/> BASIC FEE <small>(37 CFR 1.16(a), (b), or (c))</small>	N/A	N/A	N/A	
<input type="checkbox"/> SEARCH FEE <small>(37 CFR 1.16(k), (l), or (m))</small>	N/A	N/A	N/A	
<input type="checkbox"/> EXAMINATION FEE <small>(37 CFR 1.16(o), (p), or (q))</small>	N/A	N/A	N/A	
TOTAL CLAIMS <small>(37 CFR 1.16(j))</small>	minus 20 =	*	X \$ =	
INDEPENDENT CLAIMS <small>(37 CFR 1.16(h))</small>	minus 3 =	*	X \$ =	
<input type="checkbox"/> APPLICATION SIZE FEE <small>(37 CFR 1.16(s))</small>	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).			
<input type="checkbox"/> MULTIPLE DEPENDENT CLAIM PRESENT <small>(37 CFR 1.16(j))</small>				
<small>* If the difference in column 1 is less than zero, enter "0" in column 2.</small>				TOTAL

APPLICATION AS AMENDED – PART II

	(Column 1)	(Column 2)	(Column 3)	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)
AMENDMENT	09/01/2015	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR			
	Total (37 CFR 1.16(j))	* 5	Minus ** 20	= 0	X \$80 =	0
	Independent (37 CFR 1.16(h))	* 1	Minus *** 3	= 0	X \$420 =	0
	<input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))					
	<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))					
TOTAL ADD'L FEE						0

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

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

LIE
/ANNETTE SMITH/

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APPLICATION NO.	FILED DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/754,932	06/30/2015	Hitesh Batra	080618-1550	1865
22428	7890	08/07/2015	EXAMINER VALENROD, YEVGENY	
Foley & Lardner LLP 3000 K STREET N.W. SUITE 600 WASHINGTON, DC 20007-5109			ART UNIT	PAPER NUMBER
			1672	
			NOTIFICATION DATE	DELIVERY MODE
			08/07/2015	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):

ipdocketing@foley.com

Applicant-Initiated Interview Summary	Application No. 14/754,932	Applicant(s) BATRA ET AL.	
	Examiner YEVGENY VALENROD	Art Unit 1672	

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

(1) YEVGENY VALENROD. (3) _____.

(2) Alexey Sapargin. (4) _____.

Date of Interview: 04 August 2015.

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

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

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

Claim(s) discussed: 1.

Identification of prior art discussed: none.

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

Rejections under 35 USC 112 and 35 USC 102(b) were discussed. Specifically Examiners interpretation of the term "batch" was considered. No agreement was reached..

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

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

Attachment

YEVGENY VALENROD/ Primary Examiner, Art Unit 1672	
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Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

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

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

37 CFR §1.2- Business to be transacted in writing.

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

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

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

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

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

The Form provides for recordation of the following information:

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

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

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

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

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

Examiner to Check for Accuracy

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



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Table with 5 columns: APPLICATION NO., FILING DATE, FIRST NAMED INVENTOR, ATTORNEY DOCKET NO., CONFIRMATION NO. Includes application details for 14/754,932 and 22428, attorney information for Foley & Lardner LLP, examiner VALENROD, YEVGENY, art unit 1672, and notification date 08/03/2015.

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):

ipdocketing@foley.com

Office Action Summary	Application No. 14/754,932	Applicant(s) BATRA ET AL.	
	Examiner YEVGENY VALENROD	Art Unit 1672	AIA (First Inventor to File) Status No

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

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 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 6/30/15.
 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) 1-8 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) 1-8 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/inft_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 6/30/15
- 3) Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 4) Other: _____

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

DETAILED ACTION

Claim Rejections - 35 USC § 112

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

(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

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

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 3, 6, 7 and 8 rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention. The term "batch" found in claim 1 renders the above claims indefinite. Specification fails to provide a limiting definition of the term "batch" and as such meets and bounds of the said term are unclear. For the purposes of compact examination examiner will not afford patentable weights to the term "batch".

Claim Rejections - 35 USC § 102

In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

Art Unit: 1672

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 3, 6, 7 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Moriarty et al. (*J. Org. Chem.* **2004**, 69(6), 1890-1902).

On Page 1892, column 1 Moriarty discloses compound 7 which has the same structure as the instantly claimed product. On page 1902, paragraph bridging column 1 and 2, Moriarty disclose a method of preparing compound 7. In the second column 99.7% pure compound 7 is disclosed the purity of the compound is determined by HPLC. The compound in the HPLC column giving rise to the peak used to determine % composition is 100% pure and therefore meets the purity limitations found in the instant claims.

The composition of claim 8 does not recite any ingredients other than treprostinil. Limitations directed to the composition are therefore met by the disclosure of pure treprostinil by Moriarty et al.

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 claims at issue 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); and *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 a nonstatutory double patenting ground provided the reference application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO internet Web site contains terminal disclaimer forms which may be used. Please visit <http://www.uspto.gov/forms/>. The filing date of the application will determine what form 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 <http://www.uspto.gov/patents/process/file/efs/guidance/eTD-info-l.jsp>.

Claims 1-8 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 9 and 15 of U.S. Patent No. 8,497,393 ('393). Although the claims at issue are not identical, they are not patentably distinct from each other because:

Claims 9 and 15 of '393 are directed to a product comprising treprostinil (compound IV). In step (d) the salt of treprostinil is converted into its acid form providing the instantly claimed compound. Since the method of making the product of '393 and the method of making the instantly claimed product as described in the instant specification are the same, the product of '393 inherently has the instantly claimed purity.

Regarding claims 4 and 5: The specification of '393 describes the disclosed process as suitable for large scale preparation of treprostinil. '393 also describes pharmaceutical activity and uses of treprostinil. One skilled in the art would have found it obvious to prepare the product of claims 9 and 15 of '393 using the method described in those claims. Since the '393 patent describes large scale synthesis of treprostinil, one would have found it obvious to use the described method to prepare large batches of the desired product thereby arriving at the instantly claimed product.

Conclusion

Claims 1-8 are pending

Claims 1-8 are rejected

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yevgeny Valenrod whose telephone number is 571-272-9049. The examiner can normally be reached on 8:30am-5:00pm M-F.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. 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.

/YEVGENY VALENROD/
Primary Examiner, Art Unit 1672

Notice of References Cited	Application/Control No. 14/754,932	Applicant(s)/Patent Under Reexamination BATRA ET AL.	
	Examiner YEVGENY VALENROD	Art Unit 1672	Page 1 of 1

U.S. PATENT DOCUMENTS

*	Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A US-8,497,393	07-2013	Batra et al.	562/466
B	US-			
C	US-			
D	US-			
E	US-			
F	US-			
G	US-			
H	US-			
I	US-			
J	US-			
K	US-			
L	US-			
M	US-			

FOREIGN PATENT DOCUMENTS

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

NON-PATENT DOCUMENTS

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

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

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NEWS EXPRESS 27 MAY 2014 CURRENT WINDOWS VERSION IS V8.5.2.1,
AND CURRENT DISCOVER FILE IS DATED 1 JUNE 2015.

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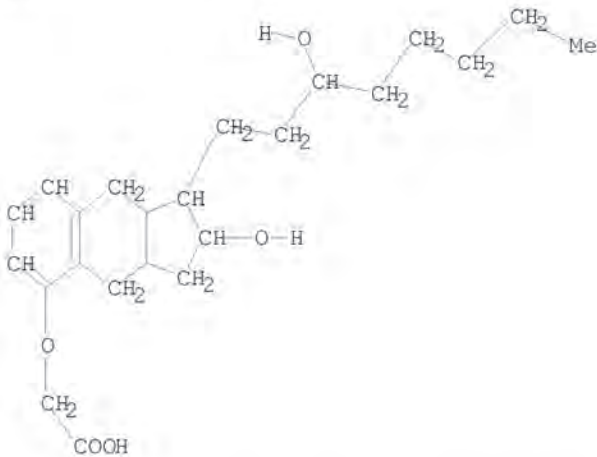
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L1 STRUCTURE UPLOADED

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Structure attributes must be viewed using the Structure Drawing program,

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SAMPLE SCREEN SEARCH COMPLETED - 10 TO ITERATE

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100.0% PROCESSED      10 ITERATIONS      3 ANSWERS
SEARCH TIME: 00.00.01

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FULL FILE PROJECTIONS:  ONLINE  **COMPLETE**
                        BATCH   **COMPLETE**
PROJECTED ITERATIONS:   11 TO    389
PROJECTED ANSWERS:      3 TO    163

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FULL SCREEN SEARCH COMPLETED - 207 TO ITERATE

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SEARCH TIME: 00.00.01

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L3          61 SEA SSS FUL L1

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COST IN U.S. DOLLARS          SINCE FILE      TOTAL
                                ENTRY      SESSION
FULL ESTIMATED COST          231.41      236.66

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FILE LAST UPDATED: 27 Jul 2015 (20150727/ED)
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USPTO MANUAL OF CLASSIFICATIONS THESAURUS ISSUE DATE: Sep 2014

CPlus includes complete International Patent Classification (IPC) reclassification data for the third quarter of 2015.

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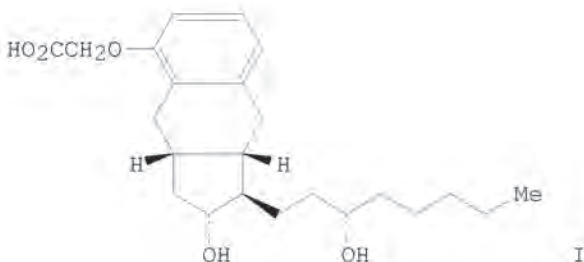
339056 HPLC
L6 1 L5 AND HPLC

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L6 ANSWER 1 OF 1 CAPLUS COPYRIGHT 2015 ACS on STN

ACCESSION NUMBER: 1988:49402 CAPLUS
DOCUMENT NUMBER: 108:49402
ORIGINAL REFERENCE NO.: 108:8081a,8084a
TITLE: High-performance liquid chromatographic method for determining the enantiomeric purity of a benzindene prostaglandin by a diastereomeric separation
AUTHOR(S): Clark, C. P.; Snider, B. G.; Bowman, P. B.
CORPORATE SOURCE: Control Res. Dev., Upjohn Co., Kalamazoo, MI, 49001, USA
SOURCE: Journal of Chromatography (1987), 408, 275-83
CODEN: JOCRAM; ISSN: 0021-9673
DIGITAL OBJECT ID: 10.1016/S0021-9673(01)81810-0
DOCUMENT TYPE: Journal
LANGUAGE: English
GI



AB An isocratic HPLC method was developed to determine the enantiomeric purity of a benzindene prostaglandin (U-62,840) (I) being evaluated for pharmaceutical applications. The enantiomers were converted to diastereomeric amide derivs. using optically pure S-(-)-1-phenylethylamine (>99.9%). Separation of the diastereomers was demonstrated on achiral silica-based stationary phases using a hexane-dioxane-water mobile phase and UV detection at 214 nm. Since an optical derivatizing agent was used, method validation addressed the issues of optical purity of the reagent and comparative rates of reaction of each enantiomer. Quant. derivatization, linearity, accuracy, precision, and ruggedness of the optimized assay conditions were demonstrated. The limit of quantitation for the enantiomeric impurity was 1.1%. A brief description of the results of a parallel study of an enantiomeric separation using various chiral HPLC columns is included.

IT 81846-19-7 112421-28-0

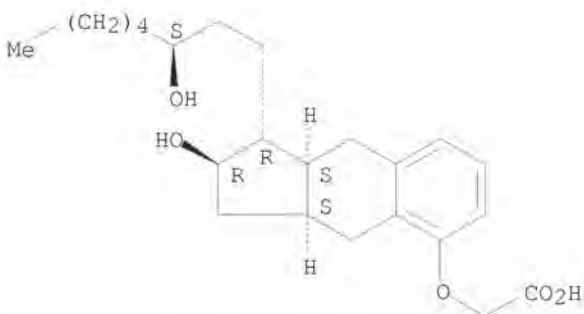
RL: PROC (Process)

(chromatog. of, for enantiomeric purification)

RN 81846-19-7 CAPLUS

CN Acetic acid, 2-[[[(1R,2R,3aS,9aS)-2,3,3a,4,9,9a-hexahydro-2-hydroxy-1-[(3S)-3-hydroxyoctyl]-1H-benz[f]inden-5-yl]oxy]- (CA INDEX NAME)

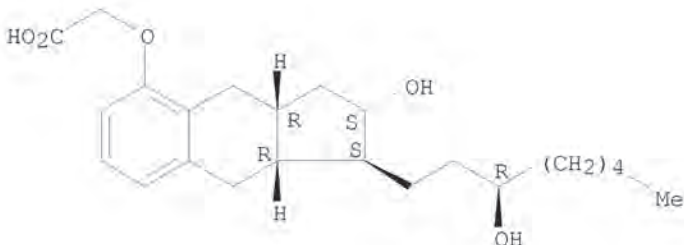
Absolute stereochemistry. Rotation (-).



RN 112421-28-0 CAPLUS

CN Acetic acid, [[2,3,3a,4,9,9a-hexahydro-2-hydroxy-1-(3-hydroxyoctyl)-1H-benz[f]inden-5-yl]oxy]-, [1S-[1α(S*),2β,3αα,9αα]]- (9CI) (CA INDEX NAME)

Absolute stereochemistry.



OS.CITING REF COUNT: 2 THERE ARE 2 CAPLUS RECORDS THAT CITE THIS RECORD
(2 CITINGS)

=> s l3 not py > 2007
363 L3
13462143 PY > 2007
L7 93 L3 NOT PY > 2007

=> s l7 and treprostinil
368 TREPROSTINIL
L8 65 L7 AND TREPROSTINIL

=> s l8 and purity
286828 PURITY
L9 0 L8 AND PURITY

=> s l8 and pure
665743 PURE
L10 0 L8 AND PURE

=> s l8 and purity
286828 PURITY
L11 0 L8 AND PURITY

=> s l8 and crystal
2027115 CRYSTAL
L12 1 L8 AND CRYSTAL

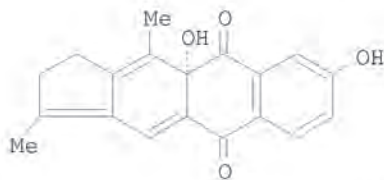
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218096 CRYSTALLIZATION
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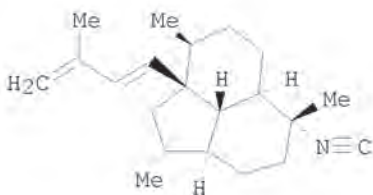
L12 ANSWER 1 OF 1 CAPLUS COPYRIGHT 2015 ACS on STN
ACCESSION NUMBER: 2005:80546 CAPLUS
DOCUMENT NUMBER: 142:336474
TITLE: Intramolecular Diels-Alder Cycloadditions of Fulvenes.
Application to the Kigelinol, Neoamphilectane, and
Kempene Skeletons
AUTHOR(S): Hong, Bor-Cherng; Chen, Fon-Len; Chen, Shang-Hung;
Liao, Ju-Hsiou; Lee, Gene-Hsiang
CORPORATE SOURCE: Department of Chemistry, National Chung Cheng
University, Chia-Yi, 621, Taiwan
SOURCE: Organic Letters (2005), 7(4), 557-560
CODEN: ORLEF7; ISSN: 1523-7060
DIGITAL OBJECT ID: 10.1021/ol047730m
PUBLISHER: American Chemical Society

DOCUMENT TYPE:
 LANGUAGE:
 OTHER SOURCE(S):
 GI

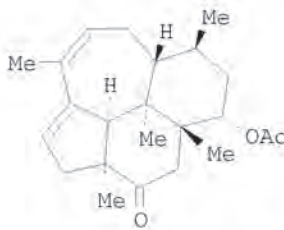
Journal
 English
 CASREACT 142:336474



I



II



III

AB A variety of polycyclic ring skeletons [e.g., kigelinol (I), neoamphilectane (II), and 2-kempene (III) systems] can be prepared rapidly via intramol. Diels-Alder cycloaddns. (IMDA) of fulvenes. The length of the tethers and the diversity of the substituents on the fulvene core dictate the nature of the IMDA pathway.

IT 81846-19-7P, Treprostiniil

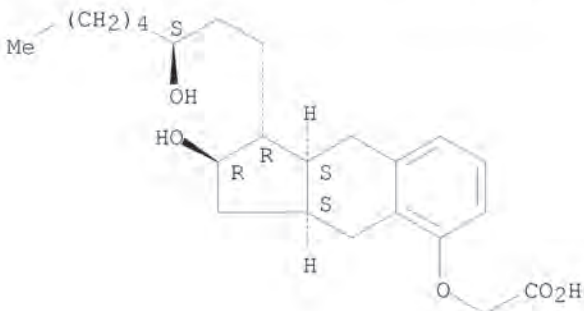
RL: PNU (Preparation, unclassified); PREP (Preparation)

(polycyclic diterpene; intramol. Diels-Alder cycloaddns. of fulvenes in the preparation of kigelinol, neoamphilectane, and kempene skeletons)

RN 81846-19-7 CAPLUS

CN Acetic acid, 2-[[[(1R,2R,3aS,9aS)-2,3,3a,4,9,9a-hexahydro-2-hydroxy-1-[(3S)-3-hydroxyoctyl]-1H-benz[f]inden-5-yl]oxy]- (CA INDEX NAME)

Absolute stereochemistry. Rotation (-).



OS.CITING REF COUNT: 40 THERE ARE 40 CAPLUS RECORDS THAT CITE THIS RECORD (41 CITINGS)
REFERENCE COUNT: 48 THERE ARE 48 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

=> s l8 and purification
510457 PURIFICATION
L14 0 L8 AND PURIFICATION

=> s treprostinil
L15 368 TREPROSTINIL

=> s l15 and large scale
1966417 LARGE
770217 SCALE
172976 LARGE SCALE
(LARGE(W)SCALE)
L16 2 L15 AND LARGE SCALE

=>

=> d l16 ibib abs hitstr 1-
YOU HAVE REQUESTED DATA FROM 2 ANSWERS - CONTINUE? Y/(N):y

L16 ANSWER 1 OF 2 CAPLUS COPYRIGHT 2015 ACS on STN
ACCESSION NUMBER: 2009:244077 CAPLUS
DOCUMENT NUMBER: 150:382562
TITLE: Crystallization Process Development for a Stable Polymorph of Treprostinil Diethanolamine (UT-15C) by Seeding
AUTHOR(S): Batra, Hitesh; Penmasta, Raju; Phares, Kenneth; Staszewski, James; Tuladhar, Sudersan M.; Walsh, David A.
CORPORATE SOURCE: Research and Development Department, United Therapeutics Corporation, Silver Spring, MD, 20910, USA
SOURCE: Organic Process Research & Development (2009), 13(2), 242-249
CODEN: OPRDFK; ISSN: 1083-6160
DIGITAL OBJECT ID: 10.1021/op800239m
PUBLISHER: American Chemical Society
DOCUMENT TYPE: Journal
LANGUAGE: English
AB Process development of treprostinil diethanolamine salt (UT-15C) involved the development of crystallization and slurry protocols to address the polymorph and morphol. control issues. Two forms of UT-15C were evaluated by differential scanning calorimetry (DSC), X-ray powder diffraction (XRPD) and thermogravimetric anal. (TGA). Two crystallization solvent systems were developed to produce the thermodynamically stable form in high quality and yield. One solvent system gave dense particles while the other gave lighter and fly-away particles. Slurrying the lighter particles in heptane converted them to denser particles. The protocol was executed successfully on large-scale cGMP batches.

OS.CITING REF COUNT: 1 THERE ARE 1 CAPLUS RECORDS THAT CITE THIS RECORD (1 CITINGS)
REFERENCE COUNT: 34 THERE ARE 34 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L16 ANSWER 2 OF 2 CAPLUS COPYRIGHT 2015 ACS on STN

ACCESSION NUMBER: 2003:184948 CAPLUS
 TITLE: Novel stereoselective route to benzindene
 prostacyclins: The large-scale synthesis of
 RemodulinTM (treprostinil, UT-15)
 AUTHOR(S): Staszewski, James P.; Moriarty, Robert M.; Guo, Liang;
 Penmasta, Raju; Rani, Neena; Tuladhar, Sudersan M.;
 Crich, David; Enache, Livia A.; Prakash, Om
 CORPORATE SOURCE: Research and Development, United Therapeutics,
 Chicago, IL, 60612, USA
 SOURCE: Abstracts of Papers, 225th ACS National Meeting, New
 Orleans, LA, United States, March 23-27, 2003 (2003),
 ORGN-455. American Chemical Society: Washington, D.
 C.
 CODEN: 69DSA4
 DOCUMENT TYPE: Conference; Meeting Abstract
 LANGUAGE: English
 AB A convergent synthesis of Remodulin- (treprostinil, 1) is described.
 This synthesis has been achieved via the use of an asym. intramol.
 Pauson-Khand Cyclization (PKC) as the key step. Treprostinil is a biol.
 important and chemical stable analog of prostacyclin (PGI₂) that has recently
 been approved for the treatment of primary and secondary pulmonary
 hypertension, a debilitating and often fatal lung disease.

=> s 18 and crystallization
 218096 CRYSTALLIZATION
 L17 0 L8 AND CRYSTALLIZATION

=> s 18 and crystals
 892618 CRYSTALS
 L18 0 L8 AND CRYSTALS

=> s treprostinil and crystals
 368 TREPROSTINIL
 892618 CRYSTALS
 L19 0 TREPROSTINIL AND CRYSTALS

=> s treprostinil and crystal
 368 TREPROSTINIL
 2027115 CRYSTAL
 L20 10 TREPROSTINIL AND CRYSTAL

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 13462143 PY > 2007
 L21 1 L20 NOT PY > 2007

=> d 121

L21 ANSWER 1 OF 1 CAPLUS COPYRIGHT 2015 ACS on STN
 AN 2005:80546 CAPLUS
 DN 142:336474
 TI Intramolecular Diels-Alder Cycloadditions of Fulvenes. Application to the
 Kigelinol, Neoamphilectane, and Kempene Skeletons
 AU Hong, Bor-Cherng; Chen, Fon-Len; Chen, Shang-Hung; Liao, Ju-Hsiou; Lee,
 Gene-Hsiang
 CS Department of Chemistry, National Chung Cheng University, Chia-Yi, 621,
 Taiwan
 SO Organic Letters (2005), 7(4), 557-560
 CODEN: ORLEF7; ISSN: 1523-7060
 DOI 10.1021/o1047730m
 PB American Chemical Society

DI Journal
LA English
OS CASREACT 142:336474
OSC.G 40 THERE ARE 40 CAPLUS RECORDS THAT CITE THIS RECORD (41 CITINGS)
RE.CNT 48 THERE ARE 48 CITED REFERENCES AVAILABLE FOR THIS RECORD
ALL CITATIONS AVAILABLE IN THE RE FORMAT

Substitute for form 1449/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Application Number	Unassigned
Date Submitted: JUN 30 2015		Filing Date	Herewith
(use as many sheets as necessary)		First Named Inventor	Hitesh BATRA
Sheet	1	Art Unit	Unassigned
	of	Examiner Name	Unassigned
	4	Attorney Docket Number	080618-1550

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)				
	A1	2002/0173672	A1	11/21/2002	Moriarty et al.	
	A2	2004/0176645	A1	09/09/2004	Moriarty et al.	
	A3	2005/0085540	A1	04/21/2005	Phares et al.	
	A4	2005/0101608	A1	05/12/2005	Santel, Donald J.	
	A5	2005/0165111	A1	07/28/2005	Wade et al.	
	A6	2005/0282903	A1	12/22/2005	Wade et al.	
	A7	2005/0282901	A1	12/22/2005	Phares et al.	
	A8	2007/0078182	A1	04/05/2007	Phares et al.	
	A9	2007/0078095	A1	04/05/2007	Phares et al.	
	A10	2008/0200449	A1	08/21/2008	Olschewski et al.	
	A11	2008/0249167	A1	10/09/2008	Phares et al.	
	A12	2008/0280986	A1	11/13/2008	Wade et al.	
	A13	2009/0036465	A1	02/05/2009	Roscigno et al.	
	A14	2009/0163738	A1	06/25/2009	Batra et al.	
	A15	4,306,076		12/15/1981	Nelson	
	A16	4,306,075	A	12/15/1981	Aristoff, Paul A.	
	A17	4,424,376	A	01/03/1984	Moniot et al.	
	A18	4,463,183	A	07/31/1984	Haslanger, Martin F.	
	A19	4,486,598	A	12/04/1984	Aristoff, Paul A.	
	A20	4,544,764	A	10/01/1985	Aristoff, Paul A.	
	A21	4,668,814	A	05/26/1987	Aristoff, Paul A.	
	A22	4,683,330	A	07/28/1987	Aristoff, Paul A.	
	A23	5,153,222	A	10/06/1992	Tadepalli et al.	
	A24	6,054,486	A	04/25/2000	Crow et al.	
	A25	6,441,245	B1	08/27/2002	Moriarty et al.	
	A26	6,521,212	B1	02/18/2003	Cloutier et al.	
	A27	6,528,688	B2	03/04/2003	Moriarty et al.	
	A28	6,700,025	B2	03/02/2004	Moriarty et al.	
	A29	6,756,033	B2	06/29/2004	Cloutier et al.	
	A30	6,765,117	B2	07/20/2004	Moriarty et al.	
	A31	6,803,386	B2	10/12/2004	Shorr et al.	
	A32	6,809,223	B2	10/26/2004	Moriarty et al.	
	A33	7,199,157	B2	04/03/2007	Wade et al.	
	A34	7,384,978	B2	06/10/2008	Phares et al.	
	A35	7,417,070	B2	08/26/2008	Phares et al.	

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. ¹	Foreign Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Documents	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ^b
		Country Code ³	Number ⁴ Kind Code ⁵ (if known)				
	A36	CA	2 710 726 A1	01/22/2012	Alphora Research Inc., CA		
	A37	CN	101891596 A	11/24/2010	Shanghai Techwell Biopharmaceutical Co. Ltd.		A ✓
	A38	CN	101891715 A	11/24/2010	Shanghai Techwell Biopharmaceutical Co. Ltd.		A ✓
	A39	EP	0 004 335 A2	10/03/1979	Hoechst AG		A
	A40	EP	0 087 237 B1	05/14/1986	The Upjohn Company		
	A41	EP	0 159 784 B1	06/07/1989	The Upjohn Company		

Examiner Signature	Date Considered
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Substitute for form 1449/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Application Number	Unassigned
Date Submitted: JUN 30 2015		Filing Date	Herewith
(use as many sheets as necessary)		First Named Inventor	Hitesh BATRA
Sheet	2	Art Unit	Unassigned
	of 4	Examiner Name	Unassigned
		Attorney Docket Number	080618-1550

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document Country Code ² Number ² Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Documents	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
	A42	EP 0 175 450 B1	03/22/1989	The Upjohn Company		
	A43	EP 0 496 548 A1	07/29/1992	Purdue Research Foundation		
	A44	JP 56-122328 A	09/25/1981	Sumitomo Chem. Co.		✓
	A45	JP 59-044340 A	03/12/1984	Sankyo Co. Ltd.		✓
	A46	WO 98/39337 A1	09/11/1998	Hoechst AG		A
	A47	WO 99/21830 A1	05/06/1999	United Therapeutics Corporation		
	A48	WO 03/070163 A2	08/28/2003	United Therapeutics Corporation		
	A49	WO 2005/007081 A2	01/27/2005	United Therapeutics Corporation		
	A50	WO 2007/134292 A2	11/22/2007	United Therapeutics Corporation		
	A51	WO 2008/100977 A2	08/21/2008	N.V. Organon		
	A52	WO 2009/117095 A1	09/24/2009	Arena Pharmaceuticals, Inc.		
	A53	WO 2012/009816 A1	01/26/2012	Alphora Research Inc.		

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	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 ⁶
	A54	ALEXANDER et al., "The Synthesis of Benzindene Prostacyclin Analogs as Potential Antiulcer Agents," Prostaglandins, 1986, 32(5):647-653.	
	A55	ARISTOFF et al., "Synthesis and Structure-Activity Relationship of Novel Stable Prostacyclin Analogs," Advances in Prostaglandin, Thromboxane, and Leukotriene Research, Samuelsson et al., Eds., 1983, 11:267-274	
	A56	ARISTOFF et al., "Synthesis of Benzopyran Prostaglandins, Potent Stable Prostacyclin Analogs, Via an Intramolecular Mistunobu Reaction," Tetrahedron Letters, 1984, 25(36):3955-3958.	
	A57	ARISTOFF et al., "Total Synthesis of a Novel Antiulcer Agent via a Modification of the Intramolecular Wadsworth-Emons-Wittig Reaction," J. Am. Chem. Soc., 1985, 107:7967-7974.	
	A58	BATRA et al., "Crystallization Process Development for a Stable Polymorph of Treprostinil Diethanolamine (UT-15C) by Seeding," Organic Process Research & Development, 2009, 13:242-249.	
	A59	BELCH et al., "Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of AS-013, a Prostaglandin E1 Prodrug, in Patients with Intermittent Claudication," Circulation, May 6, 1997, 95(9):2298-2302.	
	A60	CHEMBURKAR et al., "Dealing with the Impact of Ritonavir Polymorphs on the Late Stages of Bulk Drug Process Development," Organic Process Research & Development, 2000, 4:413-417.	
	A61	CHUNG et al., "Promoters for the (Alkyne)hexacarbonyldicobalt-Based Cyclopentenone Synthesis," Organometallics, 1993, 12:220-223.	
	A62	CLARK et al., "High-Performance Liquid Chromatographic Method for Determining the Enantiomeric Purity of a Benzindene Prostaglandin by a Diastereomeric Separation," Journal of Chromatography, 1987, 408:275-283.	

Examiner Signature	Date Considered
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Substitute for form 1449/PTO		<i>Complete if Known</i>	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT Date Submitted: <u>JUN 30 2015</u> (use as many sheets as necessary)		Application Number	Unassigned
		Filing Date	Herewith
Sheet 3 of 4		First Named Inventor	Hitesh BATRA
		Art Unit	Unassigned
		Examiner Name	Unassigned
		Attorney Docket Number	080618-1550


NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	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 ⁶
	A63	HARDINGER et al., "Triply-Convergent Syntheses of Two Homochiral Arene-Fused Prostacyclin Analogs Related to U68,215," Bioorganic & Medicinal Chemistry Letters, 1991, 1(1):79-82.	
	A64	HICKS et al., "A Practical Titanium-Catalyzed Synthesis of Bicyclic Cyclopentenones and Allylic Amines," J. Org. Chem., 1996, 61:2713-2718.	
	A65	JEONG et al., "Catalytic Version of the Intramolecular Pauson-Khand Reaction," J. Am. Chem. Soc., 1994, 116:3159-3160.	
	A66	KHAND et al., "Organocobalt Complexes. Part II. Reaction of Acetylenehexacarbonyl-dicobalt Complexes, (R ¹ C ₂ R ²)Co ₂ (CO) ₆ , with Norbornene and its Derivatives," J. Chem. Soc., J.C.S. Perkin I., 1973, 977-981.	
	A67	MATHRE et al., "A Practical Enantioselective Synthesis of α,α -Diaryl-2-pyrrolidinemethanol. Preparation and Chemistry of the Corresponding Oxazaborolidines," J. Org. Chem., 1991, 56:751-762.	
	A68	Moriarty et al., "The Intramolecular Asymmetric Pauson-Khand Cyclization as a Novel and General Stereoselective Route to Benzindene Prostacyclins: Synthesis of UT-15 (Trepstinil)," J. Org. Chem. 2004, 69, 1890-1902.	
	A69	MULZER et al., "Asymmetric Synthesis of Carbacyclin Precursors by Pauson-Khand Cyclization," Liebigs Ann. Chem., 1988, 891-897.	
	A70	NELSON, Norman A., "Prostaglandin Nomenclature," J. Med. Chem., September 1974, 17(9):911-918.	
	A71	PAGENKOPF et al., "Photochemical Promotion of the Intramolecular Pauson-Khand Reaction. A New Experimental Protocol for Cobalt-Catalyzed [2 + 2 + 1] Cycloadditions," J. Am. Chem. Soc., 1996, 118:2285-2286.	
	A72	PAGENKOPF, Brian L., "Substrate and Reagent Control of Diastereoselectivity in Transition Metal-Mediated Process: Development of a Catalytic Photo Promoted Pauson-Khand Reaction," Diss. Abstr. Int., 57(12):7535, 1977, Abstract.	
	A73	Patterson et al., "Acute Hemodynamic Effects of the Prostacyclin Analog 15AU81 in Severe Congestive Heart Failure," Am. J. Cardio., 1995, 75:26A-33A.	
	A74	PAULSON, Peter L., "The Khand Reaction," Tetrahedron, 1985, 41(24):5855-5860.	
	A75	SCHORE, Neil E., "Transition-Metal-Mediated Cycloaddition Reactions of Alkynes in Organic Synthesis," Chem. Rev., 1988, 88:1081-1119.	
	A76	SHAMBAYATI et al., "N-Oxide Promoted Pauson-Khand Cyclizations at Room Temperature," Tetrahedron Letters, 1990, 31(37):5289-5292.	
	A77	SNELL et al., "Investigating the Effect of Impurities on Macromolecule Crystal Growth in Microgravity," Crystal Growth & Design, 2001, 1(2):151-158.	
	A78	Sorbera et al. "UT-15. Treatment of Pulmonary Hypertension Treatment of Peripheral Vascular Disease," Drug of the Future, 2001, 26(4), 364-374.	
	A79	TAKANO et al., "Enantiodivergent Synthesis of Both Enantiomers of Sulcatol and Matsutake Alcohol from (R)-Epichlorohydrin," Chemistry Letters, 1987, 2017-2020.	

Examiner Signature	Date Considered
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Substitute for form 1449/PTO		<i>Complete if Known</i>	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Application Number	Unassigned
Date Submitted: JUN 30 2015		Filing Date	Herewith
<i>(use as many sheets as necessary)</i>		First Named Inventor	Hitesh BATRA
Sheet	4	Art Unit	Unassigned
	of	Examiner Name	Unassigned
	4	Attorney Docket Number	080618-1550

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	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 ⁶
	A80	VIEDMA, Cristobal, "Selective Chiral Symmetry Breaking during Crystallization: Parity Violation of Cryptochiral Environment in Control?" Crystal Growth & Design, 2007, 7(3):553-556.	
	A81	Whittle et al., "Antithrombotic Assessment and Clinical Potential of Prostacyclin Analogues," Progress in Medicinal Chemistry, Ellis et al. Eds., 1984, Chapter 6, Vol. 21, 238-279.	
	A82	ZHANG et al., "A Nickel(0)-Catalyzed Process for the Transformation of Enynes to Bicyclic Cyclopentenones," J. Org. Chem., 1996, 61:4498-4499.	

Examiner Signature	/Yevgeny Valenrod/	Date Considered	07/28/2015
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Index of Claims 	Application/Control No. 14754932	Applicant(s)/Patent Under Reexamination BATRA ET AL.
	Examiner YEVEGENY VALENROD	Art Unit 1672

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

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

CLAIM		DATE									
Final	Original	07/28/2015									
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	2	✓									
	3	✓									
	4	✓									
	5	✓									
	6	✓									
	7	✓									
	8	✓									

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
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L2	1	("8242305").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2015/07/28 13:16
L3	1	("4683330").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2015/07/28 13:16
L4	1	("4306075").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2015/07/28 13:16
L5	22	((Hitesh) near2 (Batra)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2015/07/28 13:16
L6	17	((Sudersan) near2 (Tuladhar)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2015/07/28 13:17
L7	26	((Raju) near2 (Penmasta)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2015/07/28 13:17
L8	230	((David) near2 (Walsh)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2015/07/28 13:17
L9	252	15 or 16 or 17 or 18	US-PGPUB; USPAT; USOCR	OR	ON	2015/07/28 13:17
L10	18	19 and treprostinil	US-PGPUB; USPAT; USOCR	OR	ON	2015/07/28 13:17
L11	496	c07c59/72.cpc.	US-PGPUB; USPAT; USOCR	OR	ON	2015/07/28 13:19
L12	857	(562/466).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2015/07/28 13:19
L13	1233	111 or 112	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/07/28 13:19
L14	32	113 and treprostinil	US-PGPUB; USPAT; USOCR	OR	ON	2015/07/28 13:19

EAST Search History (Prior Art)

L15	29	114 and purity	US-PGPUB; USPAT; USOCR	OR	ON	2015/07/28 13:20
L16	27	115 and HPLC	US-PGPUB; USPAT; USOCR	OR	ON	2015/07/28 13:20

EAST Search History (Interference)

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BIB DATA SHEET

CONFIRMATION NO. 1865

SERIAL NUMBER	FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.		
14/754,932	06/30/2015	562 C07C59/72	1672	080618-1550		
APPLICANTS United Therapeutics Corporation, Silver Spring, MD;						
INVENTORS Hitesh Batra, Herndon, VA; Sudersan M. Tuladhar, Silver Spring, MD; Raju Permastha, Herndon, VA; David A. Walsh, Palmyra, VA;						
** CONTINUING DATA ***** This application is a CON of 13/933,623 07/02/2013 which is a CON of 13/548,446 07/13/2012 PAT 8497393 which is a CON of 12/334,731 12/15/2008 PAT 8242305 which claims benefit of 61/014,232 12/17/2007						
** FOREIGN APPLICATIONS *****						
** IF REQUIRED, FOREIGN FILING LICENSE GRANTED ** 07/13/2015						
Foreign Priority claimed 35 USC 119(a-d) conditions met Verified and Acknowledged	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No /YEVEGENY VALENROD/ Examiner's Signature	<input type="checkbox"/> Met after Allowance Initials	STATE OR COUNTRY VA	SHEETS DRAWINGS 0	TOTAL CLAIMS 8	INDEPENDENT CLAIMS 2
ADDRESS Foley & Lardner LLP 3000 K STREET N.W. SUITE 600 WASHINGTON, DC 20007-5109 UNITED STATES						
TITLE PROCESS TO PREPARE TREPROSTINIL, THE ACTIVE INGREDIENT IN REMODULIN®						
FILING FEE RECEIVED 1600	FEES: Authority has been given in Paper No. _____ to charge/credit DEPOSIT ACCOUNT No. _____ for following:			<input type="checkbox"/> All Fees <input type="checkbox"/> 1.16 Fees (Filing) <input type="checkbox"/> 1.17 Fees (Processing Ext. of time) <input type="checkbox"/> 1.18 Fees (Issue) <input type="checkbox"/> Other _____ <input type="checkbox"/> Credit		



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Table with 7 columns: APPLICATION NUMBER, FILING or 371(c) DATE, GRP ART UNIT, FIL. FEE REC'D, ATTY/DOCKET NO, TOT CLAIMS, IND CLAIMS. Values: 14/754,932, 06/30/2015, 1629, 1600, 080618-1550, 8, 2

CONFIRMATION NO. 1865

FILING RECEIPT



22428
Foley & Lardner LLP
3000 K STREET N.W.
SUITE 600
WASHINGTON, DC 20007-5109

Date Mailed: 07/14/2015

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)

Hitesh Batra, Herndon, VA;
Sudersan M. Tuladhar, Silver Spring, MD;
Raju Penmasta, Herndon, VA;
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Applicant(s)

United Therapeutics Corporation, Silver Spring, MD;

Assignment For Published Patent Application

United Therapeutics Corporation, Silver Spring, MD

Power of Attorney: The patent practitioners associated with Customer Number 22428

Domestic Priority data as claimed by applicant

This application is a CON of 13/933,623 07/02/2013
which is a CON of 13/548,446 07/13/2012 PAT 8497393
which is a CON of 12/334,731 12/15/2008 PAT 8242305
which claims benefit of 61/014,232 12/17/2007

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 - A proper Authorization to Permit Access to Application by Participating Offices (PTO/SB/39 or its equivalent) has been received by the USPTO.

If Required, Foreign Filing License Granted: 07/13/2015

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 14/754,932**

Projected Publication Date: 10/22/2015

Non-Publication Request: No

Early Publication Request: No
Title

PROCESS TO PREPARE TREPROSTINIL, THE ACTIVE INGREDIENT IN REMODULIN®

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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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor Name: Hitesh BATRA

Title: AN IMPROVED PROCESS TO PREPARE
TREPASTINIL, THE ACTIVE INGREDIENT
IN REMODULIN®

Prior Appl. No.: 13/933,623

Prior Appl. Filing

Date: 7/2/2013

Examiner: Unassigned

Art Unit: Unassigned

CONTINUING PATENT APPLICATION
TRANSMITTAL LETTER

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

Commissioner:

Transmitted herewith for filing under 37 C.F.R. § 1.53(b) is a:

Continuation Division Continuation-In-Part (CIP)

of the above-identified copending prior application in which no patenting, abandonment, or termination of proceedings has occurred. Priority to the above-identified prior application is hereby claimed under 35 U.S.C. § 120 for this continuing application. The entire disclosure of the above-identified prior application is considered as being part of the disclosure of the accompanying continuing application and is hereby incorporated by reference therein.

Applicant claims small entity status under 37 CFR 1.27.

Enclosed are:

- Description, Claims, and Abstract (24 pages).
 - Executed Declarations (4 pages).
 - Power of Attorney (1 pages).
 - Information Disclosure Statement, Form PTO-SB08.
 - Application Data Sheet (37 CFR 1.76).
-

The adjustment to the number of sheets for EFS-Web filing follows:

Number of Sheets		EFS-Web Adjustment	Number of Sheets for EFS-Web
24	x	75%	18

The filing fee is calculated below at the large entity rate:

	Number Filed		Included in Basic Fee		Extra		Rate	=	Fee Totals
Basic Filing Fee							\$280.00	=	\$280.00
Search Fee Examination Fee							\$600.00	=	\$600.00
							\$720.00	=	\$720.00
Size Fee	18	-	100	=	0	x	\$400.00	=	\$0.00
Total	8	-	20	=	0	x	\$80.00	=	\$0.00
Claims:									
Independent:	2	-	3	=	0	x	\$420.00	=	\$0.00
If any Multiple Dependent Claim(s) present:						+	\$780.00	=	\$0.00
Surcharge under 37 CFR 1.16(e) for late filing of Executed Declaration or late payment of filing fee						+	\$140.00	=	\$0.00
Prioritized Examination fee (Track I) under 37 C.F.R. § 1.17 (e)								=	\$0.00
Processing Fee (Track I) under 37 C.F.R. § 1.17 (i)								=	\$0.00
							TOTAL FILING FEE:	=	\$1600.00
Assignment Recordation Fee:						+	\$40.00	=	\$0.00
Processing Fee under 37 CFR 1.17(i) for Late Filing of English Translation of Application:						+	\$140.00	=	\$0.00
Publication Fee								=	\$0.00
TOTAL FEE								=	\$1600.00

The above-identified fees of \$1600.00 are being paid by credit card via EFS-Web.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Please direct all correspondence to the undersigned attorney or agent at the address indicated below.

Respectfully submitted,

Date JUN 30 2015

By 

FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 672-5569
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Stephen B. Maebius
Attorney for Applicant
Registration No. 35,264

**AN IMPROVED PROCESS TO PREPARE TREPROSTINIL, THE ACTIVE
INGREDIENT IN REMODULIN[®]**

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a Continuation of U.S. Application No. 13/933,623, filed July 2, 2013, which is a Continuation of U.S. Application No. 13/548,446, filed July 13, 2012, which is a Continuation of U.S. Application No. 12/334,731, filed December 15, 2008, which claims priority from U.S. Provisional Patent Application 61/014,232, filed December 17, 2007, the entire contents of which are incorporated herein by reference.

BACKGROUND

[0002] The present invention relates to a process for producing prostacyclin derivatives and novel intermediate compounds useful in the process.

[0003] Prostacyclin derivatives are useful pharmaceutical compounds possessing activities such as platelet aggregation inhibition, gastric secretion reduction, lesion inhibition, and bronchodilation.

[0004] Treprostinil, the active ingredient in Remodulin[®], was first described in US patent 4,306,075. Treprostinil, and other prostacyclin derivatives have been prepared as described in Moriarty, et al in *J. Org. Chem.* 2004, 69, 1890-1902, *Drug of the Future*, 2001, 26(4), 364-374, U.S. Pat. Nos. 6,441,245, 6,528,688, 6,765,117 and 6,809,223. Their teachings are incorporated by reference to show how to practice the embodiments of the present invention.

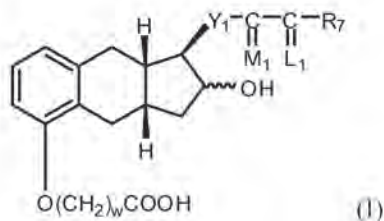
[0005] U.S. Patent No. 5,153,222 describes use of treprostinil for treatment of pulmonary hypertension. Treprostinil is approved for the intravenous as well as subcutaneous route, the latter avoiding septic events associated with continuous intravenous catheters. U.S. patents Nos. 6,521,212 and 6,756,033 describe administration of treprostinil by inhalation for treatment of pulmonary hypertension, peripheral vascular disease and other diseases and conditions. U.S. patent No. 6,803,386 discloses administration of treprostinil for treating cancer such as lung, liver, brain, pancreatic, kidney, prostate, breast, colon and head-neck cancer. U.S. patent application publication No. 2005/0165111 discloses treprostinil treatment of ischemic lesions. U.S. patent No. 7,199,157 discloses that treprostinil treatment improves kidney functions. U.S. patent application publication No. 2005/0282903 discloses treprostinil

treatment of neuropathic foot ulcers. U.S. application No. 12/028,471 filed February 8, 2008, discloses treprostinil treatment of pulmonary fibrosis. U.S. 6,054,486 discloses treatment of peripheral vascular disease with treprostinil. U.S. patent application 11/873,645 filed October 17, 2007 discloses combination therapies comprising treprostinil. U.S. publication No. 2008/0200449 discloses delivery of treprostinil using a metered dose inhaler. U.S. publication No. 2008/0280986 discloses treatment of interstitial lung disease with treprostinil. U.S. application No. 12/028,471 filed February 8, 2008 discloses treatment of asthma with treprostinil. U.S. 7,417,070, 7,384,978 and U.S. publication Nos. 2007/0078095, 2005/0282901, and 2008/0249167 describe oral formulations of treprostinil and other prostacyclin analogs.

[0006] Because Treprostinil, and other prostacyclin derivatives are of great importance from a medicinal point of view, a need exists for an efficient process to synthesize these compounds on a large scale suitable for commercial production.

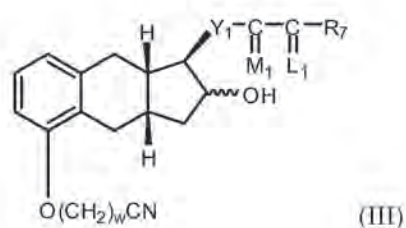
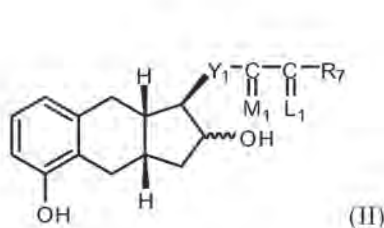
SUMMARY

[0007] The present invention provides in one embodiment a process for the preparation of a compound of formula I, hydrate, solvate, prodrug, or pharmaceutically acceptable salt thereof.



[0008] The process comprises the following steps:

- (a) alkylating a compound of structure II with an alkylating agent to produce a compound of formula III,



wherein

$w = 1, 2, \text{ or } 3;$

Y_1 is trans-CH=CH- , cis-CH=CH- , $-\text{CH}_2(\text{CH}_2)_m-$, or $-\text{C}\equiv\text{C-}$; m is 1, 2, or 3;

R_7 is

- (1) $-\text{C}_p\text{H}_{2p}-\text{CH}_3$, wherein p is an integer from 1 to 5, inclusive,
- (2) phenoxy optionally substituted by one, two or three chloro, fluoro, trifluoromethyl, (C_1-C_3) alkyl, or (C_1-C_3) alkoxy, with the proviso that not more than two substituents are other than alkyl, with the proviso that R_7 is phenoxy or substituted phenoxy, only when R_3 and R_4 are hydrogen or methyl, being the same or different,
- (3) phenyl, benzyl, phenylethyl, or phenylpropyl optionally substituted on the aromatic ring by one, two or three chloro, fluoro, trifluoromethyl, (C_1-C_3) alkyl, or (C_1-C_3) alkoxy, with the proviso that not more than two substituents are other than alkyl,

(4) $\text{cis-CH=CH-CH}_2-\text{CH}_3$,

(5) $-(\text{CH}_2)_2-\text{CH}(\text{OH})-\text{CH}_3$, or

(6) $-(\text{CH}_2)_3-\text{CH}=\text{C}(\text{CH}_3)_2$;

wherein $-\text{C}(\text{L}_1)-\text{R}_7$ taken together is

(1) (C_4-C_7) cycloalkyl optionally substituted by 1 to 3 (C_1-C_5) alkyl;

(2) 2-(2-furyl)ethyl,

(3) 2-(3-thienyl)ethoxy, or

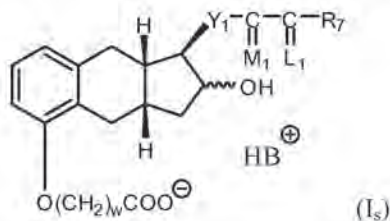
(4) 3-thienyloxymethyl;

M_1 is $\alpha\text{-OH}:\beta\text{-R}_5$ or $\alpha\text{-R}_5:\beta\text{-OH}$ or $\alpha\text{-OR}_2:\beta\text{-R}_5$ or $\alpha\text{-R}_5:\beta\text{-OR}_2$, wherein R_5 is hydrogen or methyl, R_2 is an alcohol protecting group, and

L_1 is $\alpha\text{-R}_3:\beta\text{-R}_4$, $\alpha\text{-R}_4:\beta\text{-R}_3$, or a mixture of $\alpha\text{-R}_3:\beta\text{-R}_4$ and $\alpha\text{-R}_4:\beta\text{-R}_3$, wherein R_3 and R_4 are hydrogen, methyl, or fluoro, being the same or different, with the proviso that one of R_3 and R_4 is fluoro only when the other is hydrogen or fluoro.

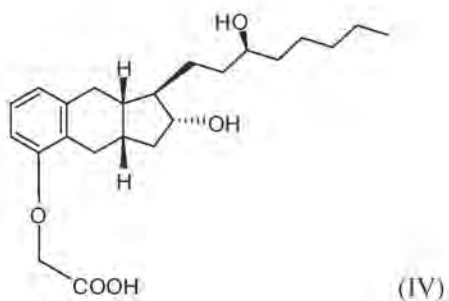
- (b) hydrolyzing the product of step (a) with a base,

- (c) contacting the product of step (b) with a base B to form a salt of formula I_s



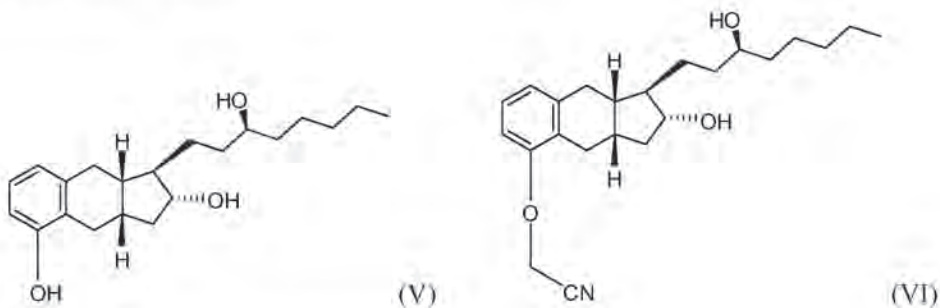
- (d) reacting the salt from step (c) with an acid to form the compound of formula I.

[0009] The present invention provides in another embodiment a process for the preparation of a compound of formula IV.



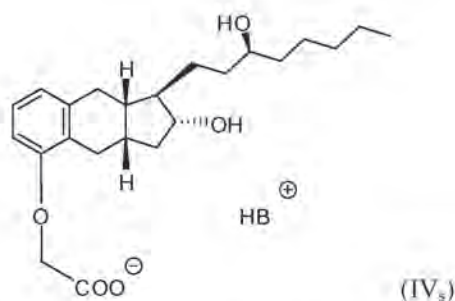
[0010] The process comprises the following steps:

- (a) alkylating a compound of structure V with an alkylating agent to produce a compound of formula VI,



- (b) hydrolyzing the product of step (a) with a base,
 (c) contacting the product of step (b) with a base B to form a salt of formula IV_s,

and



(d) reacting the salt from step (b) with an acid to form the compound of formula IV.

DETAILED DESCRIPTION

[0011] The various terms used, separately and in combinations, in the processes herein described are defined below.

[0012] The expression “comprising” means “including but not limited to.” Thus, other non-mentioned substances, additives, carriers, or steps may be present. Unless otherwise specified, “a” or “an” means one or more.

[0013] C₁₋₃-alkyl is a straight or branched alkyl group containing 1-3 carbon atoms. Exemplary alkyl groups include methyl, ethyl, n-propyl, and isopropyl.

[0014] C₁₋₃-alkoxy is a straight or branched alkoxy group containing 1-3 carbon atoms. Exemplary alkoxy groups include methoxy, ethoxy, propoxy, and isopropoxy.

[0015] C₄₋₇-cycloalkyl is an optionally substituted monocyclic, bicyclic or tricyclic alkyl group containing between 4-7 carbon atoms. Exemplary cycloalkyl groups include but not limited to cyclobutyl, cyclopentyl, cyclohexyl, and cycloheptyl.

[0016] Combinations of substituents and variables envisioned by this invention are only those that result in the formation of stable compounds. The term “stable”, as used herein, refers to compounds which possess stability sufficient to allow manufacture and which maintains the integrity of the compound for a sufficient period of time to be useful for the purposes detailed herein.

[0017] As used herein, the term “prodrug” means a derivative of a compound that can hydrolyze, oxidize, or otherwise react under biological conditions (*in vitro* or *in vivo*) to provide an active compound. Examples of prodrugs include, but are not limited to,

derivatives of a compound that include biohydrolyzable groups such as biohydrolyzable amides, biohydrolyzable esters, biohydrolyzable carbamates, biohydrolyzable carbonates, biohydrolyzable ureides, and biohydrolyzable phosphate analogues (*e.g.*, monophosphate, diphosphate or triphosphate).

[0018] As used herein, "hydrate" is a form of a compound wherein water molecules are combined in a certain ratio as an integral part of the structure complex of the compound.

[0019] As used herein, "solvate" is a form of a compound where solvent molecules are combined in a certain ratio as an integral part of the structure complex of the compound.

[0020] "Pharmaceutically acceptable" means in the present description being useful in preparing a pharmaceutical composition that is generally safe, non-toxic and neither biologically nor otherwise undesirable and includes being useful for veterinary use as well as human pharmaceutical use.

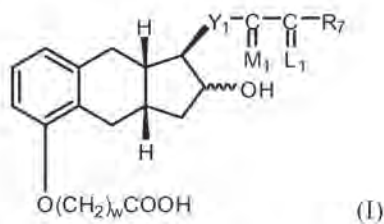
[0021] "Pharmaceutically acceptable salts" mean salts which are pharmaceutically acceptable, as defined above, and which possess the desired pharmacological activity. Such salts include acid addition salts formed with organic and inorganic acids, such as hydrogen chloride, hydrogen bromide, hydrogen iodide, sulfuric acid, phosphoric acid, acetic acid, glycolic acid, maleic acid, malonic acid, oxalic acid, methanesulfonic acid, trifluoroacetic acid, fumaric acid, succinic acid, tartaric acid, citric acid, benzoic acid, ascorbic acid and the like. Base addition salts may be formed with organic and inorganic bases, such as sodium, ammonia, potassium, calcium, ethanolamine, diethanolamine, N-methylglucamine, choline and the like. Included in the invention are pharmaceutically acceptable salts or compounds of any of the formulae herein.

[0022] Depending on its structure, the phrase "pharmaceutically acceptable salt," as used herein, refers to a pharmaceutically acceptable organic or inorganic acid or base salt of a compound. Representative pharmaceutically acceptable salts include, *e.g.*, alkali metal salts, alkali earth salts, ammonium salts, water-soluble and water-insoluble salts, such as the acetate, amsonate (4,4-diaminostilbene-2, 2'-disulfonate), benzenesulfonate, benzonate, bicarbonate, bisulfate, bitartrate, borate, bromide, butyrate, calcium, calcium edetate, camsylate, carbonate, chloride, citrate, clavulariate, dihydrochloride, edetate, edisylate, estolate, esylate, fumarate, gluceptate, gluconate, glutamate, glycolylarsanilate, hexafluorophosphate, hexylresorcinate, hydrabamine, hydrobromide, hydrochloride,

hydroxynaphthoate, iodide, isothionate, lactate, lactobionate, laurate, malate, maleate, mandelate, mesylate, methylbromide, methylnitrate, methylsulfate, mucate, napsylate, nitrate, N-methylglucamine ammonium salt, 3-hydroxy-2-naphthoate, oleate, oxalate, palmitate, pamoate (1,1-methene-bis-2-hydroxy-3-naphthoate, einbonate), pantothenate, phosphate/diphosphate, picrate, polygalacturonate, propionate, p-toluenesulfonate, salicylate, stearate, subacetate, succinate, sulfate, sulfosalicylate, suramate, tannate, tartrate, teoclate, tosylate, trithiodide, and valerate salts.

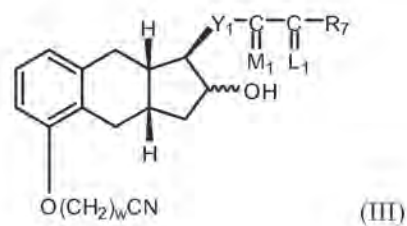
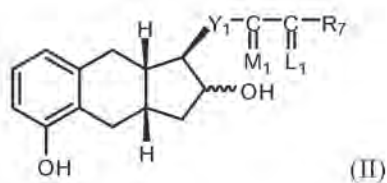
[0023] The present invention provides for a process for producing treprostinil and other prostacyclin derivatives and novel intermediate compounds useful in the process. The process according to the present invention provides advantages on large-scale synthesis over the existing method. For example, the purification by column chromatography is eliminated, thus the required amount of flammable solvents and waste generated are greatly reduced. Furthermore, the salt formation is a much easier operation than column chromatography. Moreover, it was found that the product of the process according to the present invention has higher purity. Therefore the present invention provides for a process that is more economical, safer, faster, greener, easier to operate, and provides higher purity.

[0024] One embodiment of the present invention is a process for the preparation of a compound of formula I, or a hydrate, solvate, prodrug, or pharmaceutically acceptable salt thereof.



[0025] The process comprises the following steps:

(a) alkylating a compound of formula II with an alkylating agent to produce a compound of formula III,



wherein

w = 1, 2, or 3;

Y₁ is trans-CH=CH-, cis-CH=CH-, -CH₂(CH₂)_m-, or -C≡C-; m is 1, 2, or 3;

R₇ is

- (1) -C_pH_{2p}-CH₃, wherein p is an integer from 1 to 5, inclusive,
- (2) phenoxy optionally substituted by one, two or three chloro, fluoro, trifluoromethyl, (C₁-C₃) alkyl, or (C₁-C₃)alkoxy, with the proviso that not more than two substituents are other than alkyl, with the proviso that R₇ is phenoxy or substituted phenoxy, only when R₃ and R₄ are hydrogen or methyl, being the same or different,
- (3) phenyl, benzyl, phenylethyl, or phenylpropyl optionally substituted on the aromatic ring by one, two or three chloro, fluoro, trifluoromethyl, (C₁-C₃)alkyl, or (C₁-C₃)alkoxy, with the proviso that not more than two substituents are other than alkyl,

- (4) cis-CH=CH-CH₂-CH₃,
- (5) -(CH₂)₂-CH(OH)-CH₃, or
- (6) -(CH₂)₃-CH=C(CH₃)₂;

wherein -C(L₁)-R₇ taken together is

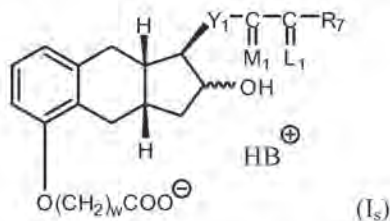
- (1) (C₄-C₇)cycloalkyl optionally substituted by 1 to 3 (C₁-C₅)alkyl;
- (2) 2-(2-furyl)ethyl,
- (3) 2-(3-thienyl)ethoxy, or
- (4) 3-thienyloxymethyl;

M₁ is α-OH:β-R₅ or α-R₅:β-OH or α-OR₂:β-R₅ or α-R₅:β-OR₂, wherein R₅ is hydrogen or methyl, R₂ is an alcohol protecting group, and

L₁ is α-R₃:β-R₄, α-R₄:β-R₃, or a mixture of α-R₃:β-R₄ and α-R₄:β-R₃, wherein R₃ and R₄ are hydrogen, methyl, or fluoro, being the same or different, with the proviso that one of R₃ and R₄ is fluoro only when the other is hydrogen or fluoro.

- (b) hydrolyzing the product of step (a) with a base,

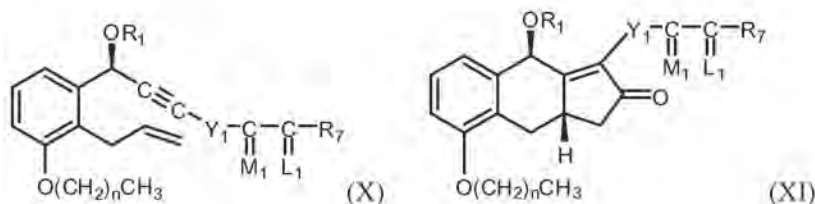
(c) contacting the product of step (b) with a base B to form a salt of formula I_s



(d) reacting the salt from step (c) with an acid to form the compound of formula I.

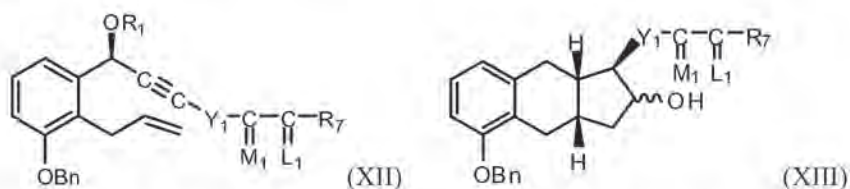
[0026] In one embodiment, the compound of formula I is at least 90.0%, 95.0%, 99.0%.

[0027] The compound of formula II can be prepared from a compound of formula XI, which is a cyclization product of a compound of formula X as described in U.S. Pat. No. 6,441,245.

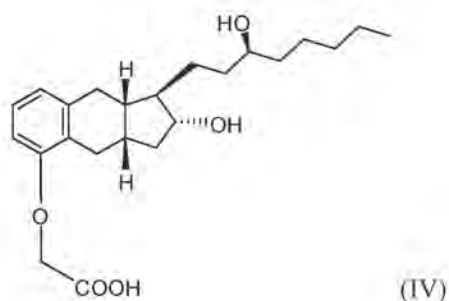


Wherein n is 0, 1, 2, or 3.

[0028] The compound of formula II can be prepared alternatively from a compound of formula XIII, which is a cyclization product of a compound of formula XII as described in U.S. Pat. No. 6,700,025.

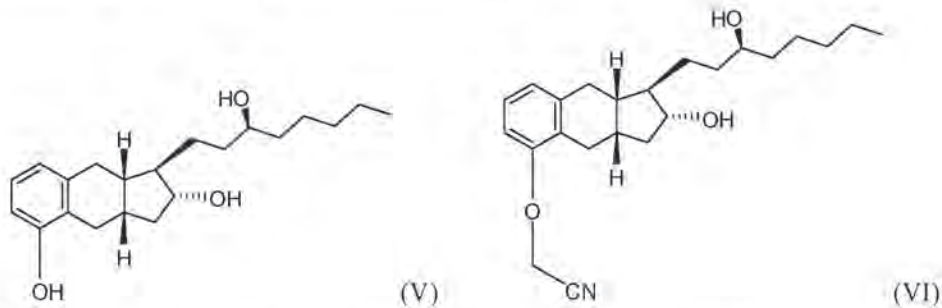


[0029] One embodiment of the present invention is a process for the preparation of a compound having formula IV, or a hydrate, solvate, or pharmaceutically acceptable salt thereof.



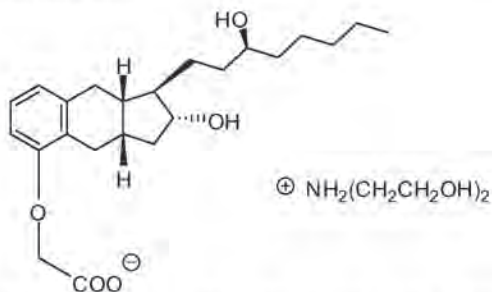
[0030] The process comprises

(a) alkylating a compound of structure V with an alkylating agent such as ClCH_2CN to produce a compound of formula VI,



(b) hydrolyzing the product of step (a) with a base such as KOH ,

(c) contacting the product of step (b) with a base B such as diethanolamine to form a salt of the following structure, and



(d) reacting the salt from step (b) with an acid such as HCl to form the compound of formula IV.

[0031] In one embodiment, the purity of compound of formula IV is at least 90.0%, 95.0%, 99.0%, 99.5%.

[0032] In one embodiment, the process further comprises a step of isolating the salt of formula IV_s.

[0033] In one embodiment, the base B in step (c) may be ammonia, N-methylglucamine, procaine, tromethamine, magnesium, L-lysine, L-arginine, or triethanolamine.

[0034] The following abbreviations are used in the description and/or appended claims, and they have the following meanings:

“MW” means molecular weight.

“Eq.” means equivalent.

“TLC” means thin layer chromatography.

“HPLC” means high performance liquid chromatography.

“PMA” means phosphomolybdic acid.

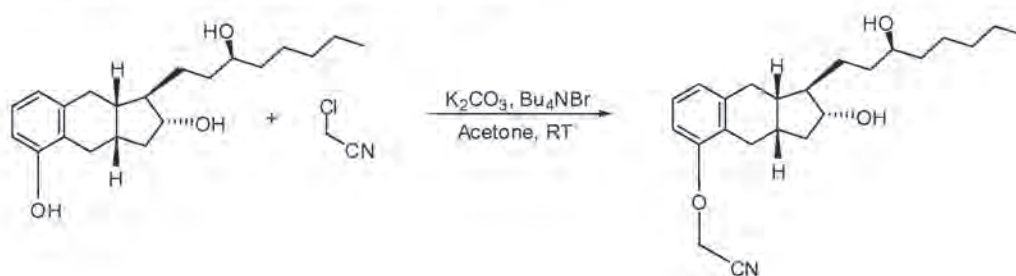
“AUC” means area under curve.

[0035] In view of the foregoing considerations, and specific examples below, those who are skilled in the art will appreciate that how to select necessary reagents and solvents in practicing the present invention.

[0036] The invention will now be described in reference to the following Examples. These examples are not to be regarded as limiting the scope of the present invention, but shall only serve in an illustrative manner.

EXAMPLES

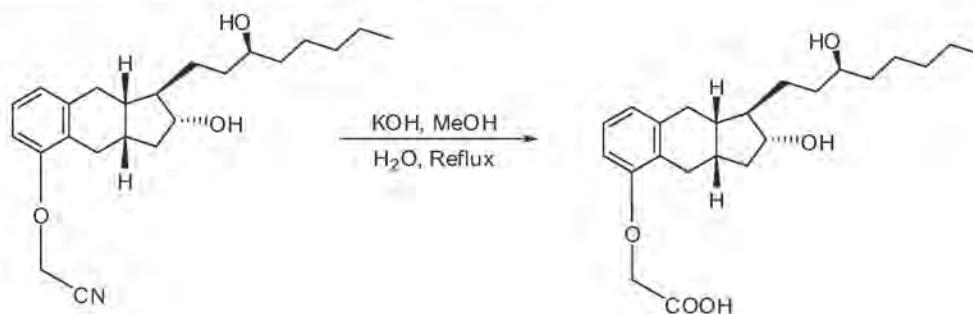
Example 1. Alkylation of Benzindene Triol



Name	MW	Amount	Mol.	Eq.
Benzindene Triol	332.48	1250 g	3.76	1.00
K ₂ CO ₃ (powder)	138.20	1296 g	9.38	2.50
ClCH ₂ CN	75.50	567 g	7.51	2.0
Bu ₄ NBr	322.37	36 g	0.11	0.03
Acetone	—	29 L	—	--
Celite [®] 545	—	115 g	—	--

[0037] A 50-L, three-neck, round-bottom flask equipped with a mechanical stirrer and a thermocouple was charged with benzindene triol (1250 g), acetone (19 L) and K₂CO₃ (powdered) (1296 g), chloroacetonitrile (567 g), tetrabutylammonium bromide (36 g). The reaction mixture was stirred vigorously at room temperature (23±2°C) for 16-72 h. The progress of the reaction was monitored by TLC. (methanol/CH₂Cl₂; 1:9 and developed by 10% ethanolic solution of PMA). After completion of reaction, the reaction mixture was filtered with/without Celite pad. The filter cake was washed with acetone (10L). The filtrate was concentrated *in vacuo* at 50-55°C to give a light-brown, viscous liquid benzindene nitrile. The crude benzindene nitrile was used as such in the next step without further purification.

Example 2. Hydrolysis of Benzindene Nitrile



Name	MW	Amount	Mol.	Eq.
Benzindene Nitrile	371.52	1397 g*	3.76	1.0
KOH	56.11	844 g	15.04	4.0
Methanol	--	12 L	--	--
Water	--	4.25 L	--	--

*Note: This weight is based on 100% yield from the previous step. This is not isolated yield.

[0038] A 50-L, cylindrical reactor equipped with a heating/cooling system, a mechanical stirrer, a condenser, and a thermocouple was charged with a solution of benzindene nitrile in methanol (12 L) and a solution of KOH (844 g of KOH dissolved in 4.25 L of water). The reaction mixture was stirred and heated to reflux (temperature 72.2°C). The progress of the reaction was monitored by TLC (for TLC purpose, 1-2 mL of reaction mixture was acidified with 3M HCl to pH 1-2 and extracted with ethyl acetate. The ethyl acetate extract was used for TLC; Eluent: methanol/CH₂Cl₂; 1:9, and developed by 10% ethanolic solution of PMA). After completion of the reaction (~5 h), the reaction mixture was cooled to -5 to 10°C and quenched with a solution of hydrochloric acid (3M, 3.1 L) while stirring. The reaction mixture was concentrated *in vacuo* at 50-55°C to obtain approximately 12-14 L of condensate. The condensate was discarded.

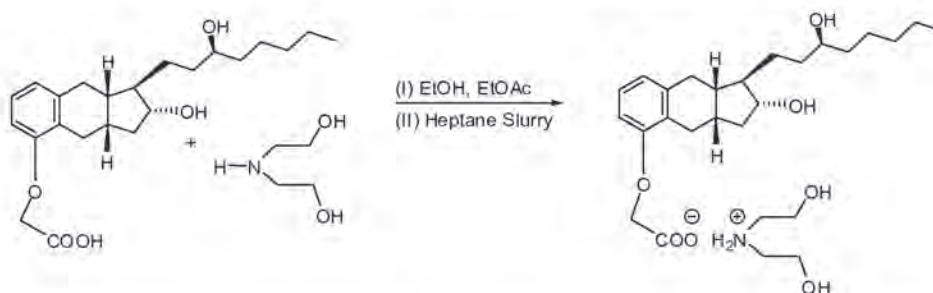
[0039] The aqueous layer was diluted with water (7-8 L) and extracted with ethyl acetate (2 × 6 L) to remove impurities soluble in ethyl acetate. To aqueous layer, ethyl acetate (22 L) was added and the pH of reaction mixture was adjusted to 1-2 by adding 3M HCl (1.7 L) with stirring. The organic layer was separated and the aqueous layer was extracted with ethyl acetate (2 × 11 L). The combined organic layers were washed with water (3 × 10 L) and followed by washing with a solution of NaHCO₃ (30 g of NaHCO₃ dissolved in 12 L of water). The organic layer was further washed with saturated solution of NaCl (3372 g of NaCl dissolved in water (12 L)) and dried over anhydrous Na₂SO₄ (950-1000 g), once filtered.

[0040] The filtrate was transferred into a 72-L reactor equipped with mechanical stirrer, a condenser, and a thermocouple. To the solution of treprostinil in reactor was added activated carbon (110-130 g). The suspension was heated to reflux (temperature 68-70°C) for at least one hour. For filtration, a pad of Celite[®] 545 (300-600 g) was prepared in sintered glass

funnel using ethyl acetate. The hot suspension was filtered through the pad of Celite[®] 545. The Celite[®] 545 was washed with ethyl acetate until no compound was seen on TLC of the washings.

[0041] The filtrate (pale-yellow) was reduced to volume of 35-40 L by evaporation *in vacuo* at 50-55°C for direct use in next step.

Example 3. Conversion of Treprostinil to Treprostinil Diethanolamine Salt (1:1)



Name	MW	Amount	Mol	Eq
Treprostinil	390.52	1464 g*	3.75	1.0
Diethanolamine	105.14	435 g	4.14	1.1
Ethanol	--	5.1 L	--	--
Ethyl acetate	--	35L**	--	--
Treprostinil Diethanolamine Salt (seed)	--	12 g	--	--

*Note: This weight is based on 100% yield from benzindene triol. It is not isolated yield. The treprostinil was carried from previous step in ethyl acetate solution and used as such for this step.

**Note: The total volume of ethyl acetate should be in range of 35-36 L (it should be 7 times the volume of ethanol used). Approximately 35 L of ethyl acetate was carried over from previous step and additional 1.0 L of ethyl acetate was used for rinsing the flask.

[0042] A 50-L, cylindrical reactor equipped with a heating/cooling system, a mechanical stirrer, a condenser, and a thermocouple was charged with a solution of treprostinil in ethyl acetate (35-40 L from the previous step), anhydrous ethanol (5.1 L) and diethanolamine (435 g). While stirring, the reaction mixture was heated to 60-75°C, for 0.5-1.0 h to obtain a clear solution. The clear solution was cooled to 55±5°C. At this temperature, the seed of

polymorph B of treprostinil diethanolamine salt (~12 g) was added to the clear solution. The suspension of polymorph B was stirred at this temperature for 1 h. The suspension was cooled to 20±2°C overnight (over a period of 16-24 h). The treprostinil diethanolamine salt was collected by filtration using Aurora filter equipped with filter cloth, and the solid was washed with ethyl acetate (2 × 8 L). The treprostinil diethanolamine salt was transferred to a HDPE/glass container for air-drying in hood, followed by drying in a vacuum oven at 50±5°C under high vacuum.

[0043] At this stage, if melting point of the treprostinil diethanolamine salt is more than 104°C, it was considered polymorph B. There is no need of recrystallization. If it is less than 104°C, it is recrystallized in EtOH-EtOAc to increase the melting point.

Data on Treprostinil Diethanolamine Salt (1:1)

Batch No.	Wt. of Benzindene Triol (g)	Wt. of Treprostinil Diethanolamine Salt (1:1) (g)	Yield (%)	Melting point (°C)
1	1250	1640	88.00	104.3-106.3
2	1250	1528	82.00*	105.5-107.2
3	1250	1499	80.42**	104.7-106.6
4	1236	1572	85.34	105-108

*Note: In this batch, approximately 1200 mL of ethyl acetate solution of treprostinil before carbon treatment was removed for R&D carbon treatment experiments.

**Note: This batch was recrystallized, for this reason yield was lower.

Example 4. Heptane Slurry of Treprostinil Diethanolamine Salt (1:1)

Name	Batch No.	Amount	Ratio
Treprostinil Diethanolamine Salt	1	3168 g	1
Heptane	--	37,5 L	12

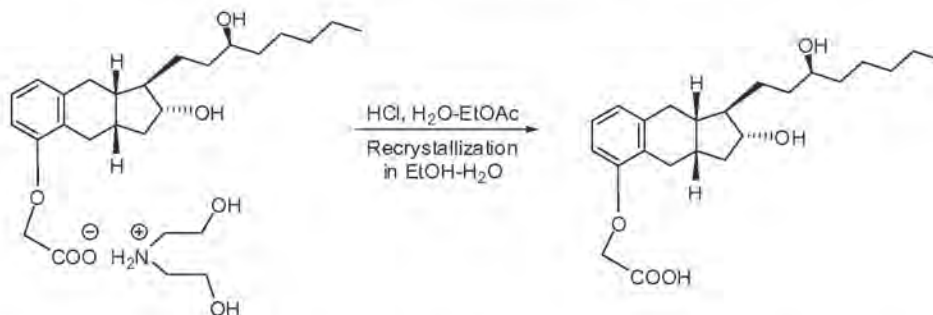
Name	Batch No.	Amount	Ratio
Treprostinil Diethanolamine Salt	2	3071 g	1
Heptane	--	36.0 L	12

[0044] A 50-L, cylindrical reactor equipped with a heating/cooling system, a mechanical stirrer, a condenser, and a thermocouple was charged with slurry of treprostinil diethanolamine salt in heptane (35-40 L). The suspension was heated to 70-80°C for 16-24 h. The suspension was cooled to 22±2°C over a period of 1-2 h. The salt was collected by filtration using Aurora filter. The cake was washed with heptane (15-30 L) and the material was dried in Aurora filter for 1 h. The salt was transferred to trays for air-drying overnight in hood until a constant weight of treprostinil diethanolamine salt was obtained. The material was dried in oven under high vacuum for 2-4 h at 50-55°C.

Analytical data on and Treprostinil Diethanolamine Salt (1:1)

Test	Batch 1	Batch 2
IR	Conforms	Conforms
Residue on Ignition (ROI)	<0.1% w/w	<0.1% w/w
Water content	0.1% w/w	0.0% w/w
Melting point	105.0-106.5°C	104.5-105.5°C
Specific rotation $[\alpha]_{589}^{25}$	+34.6°	+35°
Organic volatile impurities		
• Ethanol	• Not detected	• Not detected
• Ethyl acetate	• Not detected	• <0.05% w/w
• Heptane	• <0.05% w/w	• <0.05% w/w
HPLC (Assay)	100.4%	99.8%
Diethanolamine	Positive	Positive

Example 5. Conversion of Treprostinil Diethanolamine Salt (1:1) to Treprostinil



[0045] A 250-mL, round-bottom flask equipped with magnetic stirrer was charged with treprostinil diethanolamine salt (4 g) and water (40 mL). The mixture was stirred to obtain a clear solution. To the clear solution, ethyl acetate (100 mL) was added. While stirring, 3M HCl (3.2 mL) was added slowly until pH ~1 was attained. The mixture was stirred for 10 minutes and organic layer was separated. The aqueous layer was extracted with ethyl acetate (2×100 mL). The combined organic layers was washed with water (2×100 mL), brine (1×50 mL) and dried over anhydrous Na_2SO_4 . The ethyl acetate solution of treprostinil was filtered and the filtrate was concentrated under vacuum at 50°C to give off-white solid. The crude treprostinil was recrystallized from 50% ethanol in water (70 mL). The pure treprostinil was collected in a Buchner funnel by filtration and cake was washed with cold 20% ethanolic solution in water. The cake of treprostinil was air-dried overnight and further dried in a vacuum oven at 50°C under high vacuum to afford 2.9 g of treprostinil (Yield 91.4%, purity (HPLC, AUC, 99.8%).

Analytical data on Treprostinil from Treprostinil Diethanolamine Salt (1:1) to Treprostinil

Batch No.	Yield	Purity (HPLC)
1	91.0%	99.8% (AUC)
2	92.0%	99.9% (AUC)
3	93.1%	99.7% (AUC)
4	93.3%	99.7% (AUC)
5	99.0 %	99.8% (AUC)
6	94.6%	99.8% (AUC)

Example 6. Comparison of the former process and a working example of the process according to the present invention

Step No.	Steps	Former Process (Batch size: 500g)	Working example of the Process according to the present invention (Batch size: 5 kg)
Nitrile			
1	Triol weight	500 g	5,000 g
2	Acetone	20 L (1:40 wt/wt)	75 L (1:15 wt/wt)
3	Potassium carbonate	1,300 g (6.4 eq)	5,200 g (2.5 eq)
4	Chloroacetonitrile	470 g (4.2 eq)	2,270 g (2 eq)
5	Tetrabutylammonium bromide	42 g (0.08 eq)	145 g (0.03 eq)
6	Reactor size	72-Liter	50- gallon
7	Reflux time	8 hours	No heating, Room temperature (r.t.) 45 h
8	Hexanes addition before filtration	Yes (10 L)	No
9	Filter	Celite	Celite
10	Washing	Ethyl acetate (10 L)	Acetone (50 L)
11	Evaporation	Yes	Yes
12	Purification	Silica gel column Dichloromethane:0.5 L Ethyl acetate: 45 L Hexane: 60 L	No column
13	Evaporation after column	Yes	No
14	Yield of nitrite	109-112 %	Not checked
Treprostnil (intermediate)			
15	Methanol	7,6 L (50-L reactor)	50 L (50-gal reactor)
16	Potassium hydroxide	650 g (8 eq)	3,375g (4 eq)
17	Water	2.2 L	17 L

18	% of KOH	30%	20%
19	Reflux time	3-3.5 h	4-5 h
20	Acid used	2.6 L (3 M)	12 L (3 M)
21	Removal of impurities	3 × 3 L Ethyl acetate	2 × 20 L Ethyl acetate
22	Acidification	0.7 L	6.5 L
23	Ethyl acetate extraction	5 × 17 L = 35 L	90+45+45 = 180 L
24	Water washing	2 × 8 L	3 × 40 L
25	Sodium bicarbonate washing	Not done	120 g in 30L water + 15 L brine
26	Brine washing	Not done	1 × 40 L
27	Sodium sulfate	1 kg	Not done
28	Sodium sulfate filtration	Before charcoal, 6 L ethyl acetate	N/A
29	Charcoal	170 g, reflux for 1.5 h, filter over Celite, 11 L ethyl acetate	Pass hot solution (75°C) through charcoal cartridge and clean filter, 70 L ethyl acetate
30	Evaporation	Yes, to get solid intermediate treprostinil	Yes, adjust to 150 L solution
Treprostinil Diethanolamine Salt			
31	Salt formation	Not done	1,744 g diethanolamine, 20 L ethanol at 60-75°C.
32	Cooling	N/A	To 20°C over weekend; add 40 L ethyl acetate; cooled to 10°C
33	Filtration	N/A	Wash with 70 L ethyl acetate
34	Drying	N/A	Air-dried to constant wt., 2 days
Treprostinil (from 1.5 kg Treprostinil diethanolamine salt)			
35	Hydrolysis	N/A	15 L water + 25 L ethyl acetate + HCl
36	Extraction	N/A	2 × 10 L ethyl acetate
37	Water wash	N/A	3 × 10 L

38	Brine wash	N/A	1 × 10 L
39	Sodium sulfate	N/A	1 kg, stir
40	Filter	N/A	Wash with 6 L ethyl acetate
41	Evaporation	N/A	To get solid, intermediate Treprostinil
42	Crude drying on tray	1 or 3 days	Same
43	Ethanol & water for cryst.	5.1 L + 5.1 L	10.2 L + 10.2 L (same %)
44	Crystallization in	20-L rotavap flask	50-L jacketed reactor
45	Temperature of crystallization	2 h r.t., fridge -0°C 24 h	50°C to 0°C ramp, 0°C overnight
46	Filtration	Buchner funnel	Aurora filter
47	Washing	20% (10 L) cooled ethanol-water	20% (20 L) cooled ethanol-water
48	Drying before oven	Buchner funnel (20 h) Tray (no)	Aurora filter (2.5 h) Tray (4 days)
49	Oven drying	15 hours, 55°C	6-15 hours, 55°C
50	Vacuum	<-0.095 mPA	< 5 Torr
51	UT-15 yield weight	~ 535 g	~ 1,100 g
52	% yield from triol)	~ 91%	~ 89%
53	Purity	~ 99.0%	99.9%

[0046] The quality of treprostinil produced according to this invention is excellent. The purification of benzindene nitrile by column chromatography is eliminated. The impurities carried over from intermediate steps (i.e. alkylation of triol and hydrolysis of benzindene nitrile) are removed during the carbon treatment and the salt formation step. Additional advantages of this process are: (a) crude treprostinil salts can be stored as raw material at ambient temperature and can be converted to treprostinil by simple acidification with diluted hydrochloric acid, and (b) the treprostinil salts can be synthesized from the solution of treprostinil without isolation. This process provides better quality of final product as well as saves significant amount of solvents and manpower in purification of intermediates.

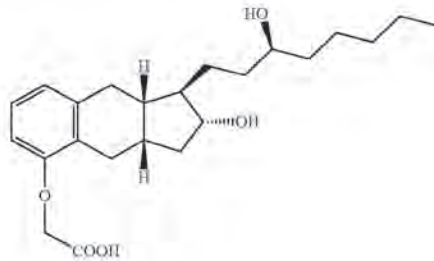
[0047] Although the foregoing refers to particular preferred embodiments, it will be understood that the present invention is not so limited. It will occur to those of ordinary skill

in the art that various modifications may be made to the disclosed embodiments and that such modifications are intended to be within the scope of the present invention.

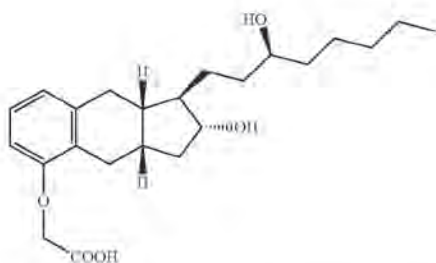
[0048] All of the publications, patent applications and patents cited in this specification are incorporated herein by reference in their entirety.

WHAT IS CLAIMED IS:

1. A high purity treprostiniil batch, wherein purity of treprostiniil in the batch is at least 99.8% as determined by HPLC and the treprostiniil in the batch has the formula:



2. The high purity treprostiniil batch of claim 1, wherein purity of treprostiniil in the batch is at least 99.9% as determined by HPLC.
3. The high purity treprostiniil batch of claim 1, wherein the batch does not contain impurities resulting from alkylation or hydrolysis of an intermediate.
4. The high purity treprostiniil batch of claim 1, which contains at least 2.9 g of treprostiniil.
5. The high purity treprostiniil batch of claim 1, which contains at least 500 g of treprostiniil.
6. The high purity treprostiniil batch of claim 1, which has been dried under vacuum.
7. A high purity treprostiniil batch, wherein the batch does not contain impurities resulting from alkylation or hydrolysis of an intermediate and the treprostiniil in the batch has the formula:



8. A pharmaceutical product comprising a therapeutically effective amount of treprostinil from a high purity treprostinil batch as claimed in claim 1.

ABSTRACT

This present invention relates to an improved process to prepare prostacyclin derivatives. One embodiment provides for an improved process to convert benzindene triol to treprostiniil via salts of treprostiniil and to purify treprostiniil.

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

080618-1256

Title of
InventionAN IMPROVED PROCESS TO PREPARE TREPROSTINIL, THE ACTIVE INGREDIENT IN
REMODULIN®

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 _____
filed on _____.

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 (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: Hitesh BATRA

Date (Optional): June 4, 2013Signature: 

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.


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

080618-1256

Title of Invention	AN IMPROVED PROCESS TO PREPARE TREPROSTINIL, THE ACTIVE INGREDIENT IN REMODULIN®	
As the below named inventor, I hereby declare that:		
This declaration is directed to:	<input checked="" type="checkbox"/>	The attached application, or
	<input type="checkbox"/>	United States application or PCT international application number _____ filed on _____.
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 (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:	Sudersan M. TULADHAR	Date (Optional): <u>June 4, 2013</u>
Signature:	<u></u>	
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.		

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

080618-1256

Title of Invention	AN IMPROVED PROCESS TO PREPARE TREPROSTINIL, THE ACTIVE INGREDIENT IN REMODULIN®
<p>As the below named inventor, I hereby declare that:</p> <p>This declaration is directed to: <input checked="" type="checkbox"/> The attached application, or <input type="checkbox"/> United States application or PCT international application number _____ filed on _____.</p> <p>The above-identified application was made or authorized to be made by me.</p> <p>I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.</p> <p>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 (5) years, or both.</p> <p style="text-align: center;">WARNING:</p> <p>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.</p>	
<p>LEGAL NAME OF INVENTOR</p> <p>Inventor: Raju PENMASTA Date (Optional): <u>Jun 04 2013</u></p> <p>Signature: <u></u></p>	
<p>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.</p>	

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.

POWER OF ATTORNEY TO PROSECUTE APPLICATIONS BEFORE THE USPTO

I hereby revoke all previous powers of attorney given in the application identified in the attached statement under 37 CFR 3.73(c).

I hereby appoint:

Practitioners associated with Customer Number: **22428**

OR

Practitioner(s) named below (if more than ten patent practitioners are to be named, then a customer number must be used):

Name	Registration Number	Name	Registration Number

As attorney(s) or agent(s) to represent the undersigned before the United States Patent and Trademark Office (USPTO) in connection with any and all patent applications assigned only to the undersigned according to the USPTO assignment records or assignments documents attached to this form in accordance with 37 CFR 3.73(c).

Please change the correspondence address for the application identified in the attached statement under 37 CFR 3.73(c) to:

The address associated with Customer Number: **22428**

OR


<input type="checkbox"/>	Firm or Individual Name		
	Address		
	City		
	Country		
	Telephone	Email	

Assignee Name and Address: **United Therapeutics Corporation
 1040 Spring Street
 Silver Spring, Maryland 20910**

A copy of this form, together with a statement under 37 CFR 3.73(c) (Form PTO/SB/96 or equivalent) is required to be Filed in each application in which this form is used. The statement under 37 CFR 3.73(c) may be completed by one of The practitioners appointed in this form, and must identify the application in which this Power of Attorney is to be filed.

SIGNATURE of Assignee of Record

The individual whose signature and title is supplied below is authorized to act on behalf of the assignee

Signature		Date	12/11/12
Name	Andrew J. Fisher	Telephone	202-742-1208
Title	Chief Strategic Officer & Deputy General Counsel		

This collection of information is required by 37 CFR 1.31, 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.

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

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	080618-1550
		Application Number	
Title of Invention	AN IMPROVED PROCESS TO PREPARE TREPROSTINIL, THE ACTIVE INGREDIENT IN REMODULIN®		
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					<input type="button" value="Remove"/>
Legal Name					
Prefix	Given Name	Middle Name	Family Name	Suffix	
	Hitesh		BATRA		
Residence Information (Select One) <input checked="" type="radio"/> US Residency <input type="radio"/> Non US Residency <input type="radio"/> Active US Military Service					
City	Herndon	State/Province	VA	Country of Residence	US
Mailing Address of Inventor:					
Address 1	2461 Leyland Ridge Road				
Address 2					
City	Herndon	State/Province	VA		
Postal Code	20171	Country i	US		
Inventor 2					<input type="button" value="Remove"/>
Legal Name					
Prefix	Given Name	Middle Name	Family Name	Suffix	
	Sudersan	M.	TULADHAR		
Residence Information (Select One) <input checked="" type="radio"/> US Residency <input type="radio"/> Non US Residency <input type="radio"/> Active US Military Service					
City	Silver Spring	State/Province	MD	Country of Residence	US
Mailing Address of Inventor:					
Address 1	1501 Haddon Manor Court				
Address 2					
City	Silver Spring	State/Province	MD		
Postal Code	20904	Country i	US		
Inventor 3					<input type="button" value="Remove"/>
Legal Name					
Prefix	Given Name	Middle Name	Family Name	Suffix	
	Raju		PENMASTA		
Residence Information (Select One) <input checked="" type="radio"/> US Residency <input type="radio"/> Non US Residency <input type="radio"/> Active US Military Service					

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	080618-1550
		Application Number	
Title of Invention	AN IMPROVED PROCESS TO PREPARE TREPROSTINIL, THE ACTIVE INGREDIENT IN REMODULIN®		

City	Herndon	State/Province	VA	Country of Residence	US
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Mailing Address of Inventor:

Address 1	12953 Centre Park Circle #115				
Address 2					
City	Herndon	State/Province	VA		
Postal Code	20171	Country	US		

Inventor 4	<input type="button" value="Remove"/>
------------	---------------------------------------

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	David	A.	WALSH	

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

City	Palmyra	State/Province	VA	Country of Residence	US
------	---------	----------------	----	----------------------	----

Mailing Address of Inventor:

Address 1	56 Wildwood Drive				
Address 2					
City	Palmyra	State/Province	VA		
Postal Code	22963	Country	US		

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

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

 An Address is being provided for the correspondence information of this application.

Customer Number	22428		
Email Address	IPDocketing@foley.com	<input type="button" value="Add Email"/>	<input type="button" value="Remove Email"/>

Application Information:

Title of the Invention	AN IMPROVED PROCESS TO PREPARE TREPROSTINIL, THE ACTIVE INGREDIENT IN REMODULIN®		
Attorney Docket Number	080618-1550	Small Entity Status Claimed	<input type="checkbox"/>
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)		Suggested Figure for Publication (if any)	1

Filing By Reference :

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	080618-1550
		Application Number	
Title of Invention	AN IMPROVED PROCESS TO PREPARE TREPROSTINIL, THE ACTIVE INGREDIENT IN REMODULIN®		

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:	<input checked="" type="radio"/> Customer Number	<input type="radio"/> US Patent Practitioner	<input type="radio"/> Limited Recognition (37 CFR 11.9)
Customer Number	22428		

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 this 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 blank.

Prior Application Status			Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
This Application	Continuation of	13/933623	2013-07-02
Prior Application Status			Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
13/933623	Continuation of	13/548446	2012-07-13
Prior Application Status			Remove

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	080618-1550
		Application Number	
Title of Invention	AN IMPROVED PROCESS TO PREPARE TREPROSTINIL, THE ACTIVE INGREDIENT IN REMODULIN®		
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
13/548446	Continuation of	12/334731	2008-12-15
Prior Application Status			<input type="button" value="Remove"/>
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
12/334731	Claims benefit of provisional	61/014232	2007-12-17
Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the Add button.			

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)¹ 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).

			<input type="button" value="Remove"/>
Application Number	Country ^j	Filing Date (YYYY-MM-DD)	Access Code ^k (if applicable)
Additional Foreign Priority Data may be generated within this form by selecting the Add button.			

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.

Authorization to Permit Access:

Authorization to Permit Access to the Instant Application by the Participating Offices

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	080618-1550
	Application Number	
Title of Invention	AN IMPROVED PROCESS TO PREPARE TREPROSTINIL, THE ACTIVE INGREDIENT IN REMODULIN®	

If 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 World Intellectual Property Office (WIPO), and any other intellectual property offices in which a foreign application claiming priority to the instant patent application is filed access to the instant patent application. See 37 CFR 1.14(c) and (h). This box should not be checked if the applicant does not wish the EPO, JPO, KIPO, WIPO, or other intellectual property office in which a foreign application claiming priority to the instant patent application is filed to have access to the instant patent application.

In accordance with 37 CFR 1.14(h)(3), access will be provided to a copy of the instant patent application with respect to: 1) the instant patent application-as-filed; 2) any foreign application to which the instant patent application claims priority under 35 U.S.C. 119(a)-(d) if a copy of the foreign application that satisfies the certified copy requirement of 37 CFR 1.55 has been filed in the instant patent application; and 3) any U.S. application-as-filed from which benefit is sought in the instant patent application.

In accordance with 37 CFR 1.14(c), access may be provided to information concerning the date of filing this Authorization.

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

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.

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: United Therapeutics Corporation

Mailing Address Information For Applicant:

Address 1	1040 Spring Street		
Address 2			
City	Silver Spring	State/Province	MD
Country	US	Postal Code	20910
Phone Number		Fax Number	

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	080618-1550
		Application Number	
Title of Invention	AN IMPROVED PROCESS TO PREPARE TREPROSTINIL, THE ACTIVE INGREDIENT IN REMODULIN®		
Email Address			
Additional Applicant Data may be generated within this form by selecting the Add button.			

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.

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.

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

Organization Name: United Therapeutics Corporation

Mailing Address Information For Assignee including Non-Applicant Assignee:

Address 1: 1040 Spring Street

Address 2:

City: Silver Spring State/Province: MD

Country: US Postal Code: 20910


Phone Number: Fax Number:

Email Address:

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

Signature:

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

Signature			Date (YYYY-MM-DD)	JUN 30 2015
First Name	Stephen B.	Last Name	Maebius	Registration Number 35264

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

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	080618-1550
	Application Number	
Title of Invention	AN IMPROVED PROCESS TO PREPARE TREPROSTINIL, THE ACTIVE INGREDIENT IN REMODULIN®	

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor Name: Hitesh BATRA
Title: AN IMPROVED PROCESS TO PREPARE
TREPASTINIL, THE ACTIVE INGREDIENT IN
REMODULIN®
Appl. No.: Unassigned (CON of 13/933623)
Filing Date: Herewith
Examiner: Unassigned
Art Unit: Unassigned

INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.56

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

Commissioner:

Applicant submits herewith documents for the Examiner's consideration in accordance with 37 CFR §§1.56, 1.97 and 1.98.

Applicant respectfully requests that each listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

Applicant requests that, in accordance with 37 CFR §1.98(d), the Examiner review all applications relied on for an earlier effective filing date under 35 U.S.C. 120, including application no. 12/334,731, filed 12/15/2008; application no. 13/548,446, filed 7/13/2012; application no. 13/933,623, filed 7/2/2013, for copies of references of record therein that are not being provided here; although Applicant would be pleased to provide copies of any such documents at the Examiner's request.

The submission of any document herewith is not an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document submitted herewith.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

Although Applicant believes that no fee is required, the Commissioner is hereby authorized to charge any additional fees which may be due to Deposit Account No. 19-0741.

Respectfully submitted,

Date JUN 30 2015

FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 672-5569
Facsimile: (202) 672-5399

By 

Stephen B. Maebius
Attorney for Applicant
Registration No. 35,264

Substitute for form 1449/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Application Number	Unassigned
Date Submitted: JUN 30 2015		Filing Date	Herewith
<i>(use as many sheets as necessary)</i>		First Named Inventor	Hitesh BATRA
Sheet	1	of	4
		Art Unit	Unassigned
		Examiner Name	Unassigned
		Attorney Docket Number	080618-1550

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)				
	A1	2002/0173672	A1	11/21/2002	Moriarty et al.	
	A2	2004/0176645	A1	09/09/2004	Moriarty et al.	
	A3	2005/0085540	A1	04/21/2005	Phares et al.	
	A4	2005/0101608	A1	05/12/2005	Santel, Donald J.	
	A5	2005/0165111	A1	07/28/2005	Wade et al.	
	A6	2005/0282903	A1	12/22/2005	Wade et al.	
	A7	2005/0282901	A1	12/22/2005	Phares et al.	
	A8	2007/0078182	A1	04/05/2007	Phares et al.	
	A9	2007/0078095	A1	04/05/2007	Phares et al.	
	A10	2008/0200449	A1	08/21/2008	Olschewski et al.	
	A11	2008/0249167	A1	10/09/2008	Phares et al.	
	A12	2008/0280986	A1	11/13/2008	Wade et al.	
	A13	2009/0036465	A1	02/05/2009	Roscigno et al.	
	A14	2009/0163738	A1	06/25/2009	Batra et al.	
	A15	4,306,076		12/15/1981	Nelson	
	A16	4,306,075	A	12/15/1981	Aristoff, Paul A.	
	A17	4,424,376	A	01/03/1984	Moniot et al.	
	A18	4,463,183	A	07/31/1984	Haslanger, Martin F.	
	A19	4,486,598	A	12/04/1984	Aristoff, Paul A.	
	A20	4,544,764	A	10/01/1985	Aristoff, Paul A.	
	A21	4,668,814	A	05/26/1987	Aristoff, Paul A.	
	A22	4,683,330	A	07/28/1987	Aristoff, Paul A.	
	A23	5,153,222	A	10/06/1992	Tadepalli et al.	
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Examiner Initials*	Cite No. ¹	Foreign Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Documents	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁵
		Country Code ³	Number ⁴ Kind Code ⁵ (if known)				
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	A37	CN	101891596 A	11/24/2010	Shanghai Techwell Biopharmaceutical Co. Ltd.		A ✓
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Examiner Signature		Date Considered	
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Substitute for form 1449/PTO			Complete if Known		
INFORMATION DISCLOSURE STATEMENT BY APPLICANT			Application Number	Unassigned	
Date Submitted: JUN 30 2015			Filing Date	Herewith	
(use as many sheets as necessary)			First Named Inventor	Hitesh BATRA	
Sheet	2	of	4	Art Unit	Unassigned
				Examiner Name	Unassigned
				Attorney Docket Number	080618-1550

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document Country Code ² Number ³ Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Documents	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
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Examiner Initials*	Cite No. ¹	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 ⁶
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Examiner Signature	Date Considered
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Substitute for form 1449/PTO		<i>Complete if Known</i>	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Application Number	Unassigned
		Filing Date	Herewith
Date Submitted: <u>JUN 30 2015</u>		First Named Inventor	Hitesh BATRA
(use as many sheets as necessary)		Art Unit	Unassigned
		Examiner Name	Unassigned
Sheet	3	of	4
		Attorney Docket Number	080618-1550

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Examiner Initials*	Cite No. ¹	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 ⁶
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Examiner Signature	Date Considered
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Substitute for form 1449/PTO		<i>Complete if Known</i>	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Application Number	Unassigned
Date Submitted: JUN 30 2015		Filing Date	Herewith
<i>(use as many sheets as necessary)</i>		First Named Inventor	Hitesh BATRA
Sheet	4	Art Unit	Unassigned
	of	Examiner Name	Unassigned
	4	Attorney Docket Number	080618-1550

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Examiner Signature	Date Considered
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Electronic Patent Application Fee Transmittal

Application Number:				
Filing Date:				
Title of Invention:	AN IMPROVED PROCESS TO PREPARE TREPROSTINIL, THE ACTIVE INGREDIENT IN REMODULIN®			
First Named Inventor/Applicant Name:	Hitesh Batra			
Filer:	Kristel Schorr/Karen Walker			
Attorney Docket Number:	080618-1550			
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	280	280
Utility Search Fee	1111	1	600	600
Utility Examination Fee	1311	1	720	720
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 (\$)				1600

Electronic Acknowledgement Receipt

EFS ID:	22782292
Application Number:	14754932
International Application Number:	
Confirmation Number:	1865
Title of Invention:	AN IMPROVED PROCESS TO PREPARE TREPROSTINIL, THE ACTIVE INGREDIENT IN REMODULIN®
First Named Inventor/Applicant Name:	Hitesh Batra
Customer Number:	22428
Filer:	Kristel Schorr/Karen Walker
Filer Authorized By:	Kristel Schorr
Attorney Docket Number:	080618-1550
Receipt Date:	30-JUN-2015
Filing Date:	
Time Stamp:	11:57:54
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	\$ 1600
RAM confirmation Number	11304
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal of New Application	Transmittal.pdf	115061 50b6e90518cc15e3bf8872350891189054e23521	no	4

Warnings:

Information:

2		Specification.pdf	255113 60ab24c37f118081b30c72033718b0716a36c3	yes	24
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Multipart Description/PDF files in .zip description

Document Description	Start	End
Specification	1	21
Claims	22	23
Abstract	24	24

Warnings:

Information:

3	Oath or Declaration filed	Declaration.pdf	256572 1710181050481a91210a1e9875ad48ac1852bc	no	4
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4	Power of Attorney	POA.pdf	116513 77f6d075a9992113d96f41c3e22c180207a000	no	1
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