UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/914,996	08/12/2014	8802107	5050E	8796

26693 7590 07/23/2014
REGENERON PHARMACEUTICALS, INC
777 OLD SAW MILL RIVER ROAD
TARRYTOWN, NY 10591

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):

Regeneron Pharmaceuticals, Inc., Tarrytown, NY, Assignee (with 37 CFR 1.172 Interest);
Eric FURFINE, Concord, MA;
Daniel DIX, LaGrangeville, NY;
Kenneth GRAHAM, Pleasant Valley, NY;
Kelly FRYE, Mendham, NJ;

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

CELLTRION EXHIBIT - 1043
Celltrion, Inc. v. Regeneron Pharmaceuticals, Inc.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/914,996	06/11/2013	Eric FURFINE	5050E	8796

26693 7590 06/25/2014
REGENERON PHARMACEUTICALS, INC
777 OLD SAW MILL RIVER ROAD
TARRYTOWN, NY 10591

EXAMINER
LOCKARD, JON MCCLELLAND

ART UNIT	PAPER NUMBER
1647	

NOTIFICATION DATE	DELIVERY MODE
06/25/2014	ELECTRONIC

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

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

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

patents@regeneron.com

CORRECTED Notice of Allowability	Application No. 13/914,996	Applicant(s) FURFINE ET AL.	
	Examiner JON M. LOCKARD	Art Unit 1647	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 *the Amendment filed 07 April 2014*.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on_____.
2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
3. ☒ The allowed claim(s) is/are *17,18 and 20-35 (renumbered as claims 1,9,2-4,10-13,5-8 and 14-18, respectively)*. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov .
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   Certified copies:

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

   * Certified copies not received: _____.

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

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

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

Attachment(s)

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

/J. M. L./ Examiner, Art Unit 1647	/Christine J Saoud/ Primary Examiner, Art Unit 1647

EXAMINER'S COMMENT

1. A corrected Notice of Allowability is being mailed to correct the renumbering of the claims.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jon M. Lockard** whose telephone number is **(571) 272-2717**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joanne Hama**, can be reached on **(571) 272-2911**. The fax 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.

/J. M. L./
Examiner, Art Unit 1647
June 20, 2014

/Christine J Saoud/
Primary Examiner, Art Unit 1647

UNITED STATES PATENT AND TRADEMARK OFFICE

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United States Patent and Trademark Office
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NOTICE OF ALLOWANCE AND FEE(S) DUE

26693 7590 04/25/2014
REGENERON PHARMACEUTICALS, INC
777 OLD SAW MILL RIVER ROAD
TARRYTOWN, NY 10591

EXAMINER
LOCKARD, JON MCCLELLAND

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 04/25/2014

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/914,996	06/11/2013	Eric FURFINE	5050E	8796

TITLE OF INVENTION: VEGF Antagonist Formulations for Intravitreal Administration

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$960	$0	$0	$960	07/25/2014

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

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

HOW TO REPLY TO THIS NOTICE:

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

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

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

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

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

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

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

PART B - FEE(S) TRANSMITTAL

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

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

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

26693 7590 04/25/2014
REGENERON PHARMACEUTICALS, INC
777 OLD SAW MILL RIVER ROAD
TARRYTOWN, NY 10591

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

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

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/914,996	06/11/2013	Eric FURFINE	5050E	8796

TITLE OF INVENTION: VEGF Antagonist Formulations for Intravitreal Administration

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$960	$0	$0	$960	07/25/2014

EXAMINER	ART UNIT	CLASS-SUBCLASS
LOCKARD, JON MCCLELLAND	1647	424-192100

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

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

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

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

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

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

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

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

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

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

UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/914,996	06/11/2013	Eric FURFINE	5050E	8796

26693 7590 04/25/2014
REGENERON PHARMACEUTICALS, INC
777 OLD SAW MILL RIVER ROAD
TARRYTOWN, NY 10591

EXAMINER
LOCKARD, JON MCCLELLAND

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 04/25/2014

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

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

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

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

Notice Requiring Inventor's Oath or Declaration	Application No. 13/914,996	Applicant(s) Eric FURFINE	
	Examiner LOCKARD, JON MCCLELLAND	Art Unit 1647	

This notice is an attachment to the Notice of Allowability (PTOL-37), or the Notice of Allowability For A Design Application (PTOL-37D).

An inventor's oath or declaration in compliance with 37 CFR 1.63 or 1.64 executed by or with respect to each inventor has not yet been submitted.

An oath or declaration in compliance with 37 CFR 1.63, or a substitute statement in compliance with 37 CFR 1.64, executed by or with respect to each inventor (for any inventor for which a compliant oath, declaration, or substitute statement has not yet been submitted) MUST be filed no later than the date on which the issue fee is paid. See 35 U.S.C. 115(f). Failure to timely comply will result in ABANDONMENT of this application.

A properly executed inventor's oath to declaration has not been received for the following inventor(s):

If applicant previously filed one or more oaths, declarations, or substitute statements, applicant may have received an informational notice regarding deficiencies therein.

The following deficiencies are noted:

INFORMAL ACTION PROBLEMS

- A properly executed inventor's oath or declaration has not been received for the following inventor(s): **Eric FURFINE**, **Daniel DIX**, **Kenneth GRAHAM**, and **Kelly FRYE**.
  Applicant may submit the inventor's oath or declaration at any time before the Notice of Allowance and Fee(s) Due, PTOL-85, is mailed.

Questions relating to this Notice should be directed to the Application Assistance Unit at 571-272-4200.

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

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

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

Privacy Act Statement

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

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

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

Notice of Allowability	Application No. 13/914,996	Applicant(s) FURFINE ET AL.	
	Examiner JON M. LOCKARD	Art Unit 1647	AIA (First Inventor to File) Status No

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

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1. ☒ This communication is responsive to *the Amendment filed 07 April 2014*.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on_____.
2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
3. ☒ The allowed claim(s) is/are *17,18 and 20-35 (renumbered as claims 1,10,2-4,11-18 and 5-9, respectively)*. 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.
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5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

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

Attachment(s)

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

/J. M. L./ Examiner, Art Unit 1647	/Christine J Saoud/ Primary Examiner, Art Unit 1647

Docket No.: 5050E

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent Application of: FURFINE et al.	Confirmation No.: 8796
Application No.: 13/914,996	Art Unit: 1647
Filed: 06/11/2013	Examiner: LOCKARD, Jon M.
For: VEGF Antagonist Formulations Suitable for Inravitreal Administration	Customer Number: 26693

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

Dear Madame Commissioner:

AMENDMENT UNDER 37 CFR § 1.111

Applicants submit this amendment and remarks in response to the non-final Office action which was mailed on October 8, 2013 and due for reply by January 8, 2014. Since this response is submitted within the third month past the shortened statutory period for reply, Applicants petition the Commissioner for a three-month extension of time according to §1.136(a), and authorize the Commissioner to deduct the required three-month extension fee of $1,400 according to §1.17(a)(3) from deposit account no. 18-0650. Applicants respectfully request the Office to consider the amendments and remarks provided in this paper, and to reconsider the claims for patenting.

The amendment to the Specification begins on page 2.

Amendments to the claims begin on page 3.

Remarks begin on page 6.

Applicants also file an eTerminal Disclaimer with this response.

AMENDMENT TO THE SPECIFICATION

Cross-Reference to Related Applications

Please amend paragraph **[0001]**, found on page 1 as follows:

> **[0001]** This application is a continuation application of U.S. patent application Ser. No. 13/329,770, filed Dec. 19, 2011, which issued as U.S. Patent No. 8,481,046, which is a continuation application of U.S. patent application Ser. No. 12/833,417, filed Jul. 9, 2010, which issued as U.S. Pat. No. 8,092,803 on Jan. 10, 2012, which is a continuation application of U.S. patent application Ser. No. 12/560,885, filed Sep. 16, 2009, which issued as U.S. Pat. No. 7,807,164 on Oct. 5, 2010, which is a divisional application of U.S. patent application Ser. No. 11/818,463, filed 14 Jun. 2007, which issued as U.S. Pat. No. 7,608,261 on Oct. 27, 2009, which claims the benefit under 35 U.S.C. § 119(e) of U.S. Provisional Application No. 60/814,484, filed 16 Jun. 2006, which applications are each hereby incorporated by reference.

AMENDMENTS TO THE CLAIMS

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

Claims 1 – 16. (Canceled).

17. (Currently amended) A method of producing a lyophilized formulation of a VEGF antagonist, comprising a step of subjecting to lyophilization a ~~the~~ pre-lyophilized formulation ~~of claim 8 to lyophilization~~, which comprises:

(a) 5-50 mg/ml of a vascular endothelial growth factor (VEGF) antagonist, comprising the amino acids 27-457 of SEQ ID NO:4;

(b) 5-25 mM of sodium phosphate buffer, pH about 5.8-7.0;

(c) 0.01-0.15% of an organic co-solvent, selected from the group consisting of polysorbate, polyethylene glycol (PEG), propylene glycol, and a combination thereof; and,

(d) 1-10% of a stabilizing agent selected from the group consisting of sucrose, sorbitol, glycerol, trehalose, and mannitol, to generate a lyophilized formulation.

18. (Currently amended) A method of producing a lyophilized formulation of a VEGF antagonist, comprising the step of subjecting ~~the pre-lyophilized formulation of claim 12~~ to lyophilization a prelyophilization formulation, which comprises

(a) 5-50 mg/ml of a vascular endothelial growth factor (VEGF) antagonist, comprising amino acids 27-457 of SEQ ID NO:4;

(b) 5-25 mM of a phosphate buffer, pH about 5.8-7.0;

(c) 0.01-0.15% of an organic co-solvent, selected from the group consisting of polysorbate, polyethylene glycol (PEG), propylene glycol, and a combination thereof; and

(d) 20-150 mM of a tonicity agent, to generate a lyophilized formulation.

19. (Canceled)

20. (new) The method of claim 17, wherein the prelyophilization formulation comprises about 20 mg/ml of the VEGF antagonist, about 10 mM sodium phosphate buffer, about 0.03% polysorbate, about 0.1% PEG, and about 2.5% sucrose, pH about 6.2-6.3.

21. (new) The method of claim 17, wherein the prelyophilization formulation comprises about 20 mg/ml of the VEGF antagonist, about 5 mM sodium phosphate buffer, about 0.015% polysorbate, about 2.5% sucrose, and further comprising sodium chloride at about 20 mM, pH about 6.2-6.3.

22. (new) The method of claim 17, wherein the prelyophilization formulation comprises about 20 mg/ml of the VEGF antagonist, about 5 mM sodium phosphate buffer, about 0.015% polysorbate, and further comprising sodium chloride at about 67.5 mM, pH about 6.2-6.3.

23. (new) The method of claim 18, wherein the tonicity agent is sodium chloride at a concentration selected from the group consisting of 20 mM and 67.5 mM.

24. (new) The method of claim 18, wherein the organic co-solvent is polysorbate at 0.015%.

25. (new) The method of claim 18, wherein the VEGF antagonist is at a concentration selected from the group consisting of 5 mg/ml, 10 mg/ml, 20 mg/ml, and 40 mg/ml.

26. (new) The method of claim 18, wherein the sodium phosphate buffer is at 5 mM.

27. (new) A lyophilized formulation made according to the method of claim 17.

28. (new) The lyophilized formulation of claim 27, wherein the prelyophilization formulation comprises about 20 mg/ml of the VEGF antagonist, about 10 mM sodium phosphate buffer, about 0.03% polysorbate, about 0.1% PEG, and about 2.5% sucrose, pH about 6.2-6.3.

29. (new) The lyophilized formulation of claim 27, wherein the prelyophilization formulation comprises about 20 mg/ml of the VEGF antagonist, about 5 mM sodium phosphate buffer, about 0.015% polysorbate, about 2.5% sucrose, and further comprising sodium chloride

at about 20 mM, pH about 6.2-6.3.

30. (new) The lyophilized formulation of claim 27, wherein the prelyophilization formulation comprises about 20 mg/ml of the VEGF antagonist, about 5 mM sodium phosphate buffer, about 0.015% polysorbate, and further comprising sodium chloride at about 67.5 mM, pH about 6.2-6.3.

31. (new) A lyophilized formulation made according to the method of claim 18.

32. (new) The lyophilized formulation of claim 31, wherein the tonicity agent is sodium chloride at a concentration selected from the group consisting of 20 mM and 67.5 mM.

33. (new) The lyophilized formulation of claim 31, wherein the organic co-solvent is polysorbate at 0.015%.

34. (new) The lyophilized formulation of claim 31, wherein the VEGF antagonist is at a concentration selected from the group consisting of 5 mg/ml, 10 mg/ml, 20 mg/ml, and 40 mg/ml.

35. (new) The lyophilized formulation of claim 31, wherein the sodium phosphate buffer is at 5 mM.

REMARKS

STATUS OF THE CLAIMS

Claims 1-19 are pending, all of which stand rejected on the ground of nonstatutory obviousness-type double patenting. Claims 1-16 and 19 are currently canceled without prejudice or disclaimer. Claims 17 and 18 are currently amended, incorporating the subject matter of claims 8 and 12, respectively. Claims 20-35 are newly presented and incorporate the subject matter of claims 9-11 and 13-16. No new matter is presented by the amendments to claims 17 and 18, or by the newly presented claims 20-35.

OBJECTION TO THE SPECIFICATION

The Office objected to the first paragraph of the description for referring only to the application number of a recently granted patent, but not to the patent number. Applicants have amended the specification to include the patent number, which is U.S. Patent No. 8,481,046 in reference to U.S. Application No. 13/329,770. Applicants request that the Office withdraw its rejection in view of the change.

DOUBLE PATENTING REJECTIONS

Claims 1-16 and 19

Claims 1-16 and 19 are rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over (1) claims 1-19 of U.S. Patent No. 8,092,803, (2) claims 1-17 of U.S. Patent No. 7,608,261, and (3) claims 1-2 of U.S. Patent No. 7,531,173. Applicants have canceled claims 1-16 and 19, thereby rendering moot this rejection. Although the subject matter of claims 9-11 and 13-16 are maintained in new claims 20-35, those claims are dependent upon claims 17 and 18, which are not subject to this rejection.

Claims 17 and 18

Claims 17 and 18 are rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over (1) claims 1-9 of U.S. Patent No. 7,807,164, and (2) claims 1-9 of U.S. Patent No. 8,481,046. In order to promote prosecution, but not to acquiesce to the Office's allegations regarding obviousness, Applicants submit a Terminal

Disclaimer via the USPTO EFS-Web system (eTerminal Disclaimer), disclaiming the terminal part of any patent granted from this application which would extend beyond the expiration date of the full statutory term of the earliest to expire of U.S. Patent No. 7,807,164 and U.S. Patent No. 8,481,046, both of which are commonly owned with the instant application. The Terminal Disclaimer overcomes the nonstatutory obviousness-type double patenting rejection of claims 17 and 18.

CONCLUSION

Applicants respectfully request the Office to reconsider the claims in view of the remarks, amendments, and Terminal Disclaimer, to withdraw the objection and rejections to the description and claims, and to issue a notice of allowance. If any other issue remains in this case, the Examiner is invited to call Undersigned Agent for the Applicants.

Dated: April 7, 2014

Respectfully submitted,

By /*Joseph E. Zahner*/

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13/914,996	06/11/2013	Eric FURFINE	5050E	8796

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EXAMINER
LOCKARD, JON MCCLELLAND

ART UNIT	PAPER NUMBER
1647	

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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.

Office Action Summary	Application No. 13/914,996	Applicant(s) FURFINE ET AL.	
	Examiner JON M. LOCKARD	Art Unit 1647	AIA (First Inventor to File) Status No

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

Period for Reply

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

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

Status

1)☒ Responsive to communication(s) filed on *11 June 2013*.

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

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

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

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

Disposition of Claims

5)☒ Claim(s) *1-19* 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) *1-19* is/are rejected.

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

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

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

Application Papers

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

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

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

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

Priority under 35 U.S.C. § 119

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

Certified copies:

a)☐ All b)☐ Some * c)☐ None of the:

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

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

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

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

Attachment(s)

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

2) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/11/13*.

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

4) ☐ Other: _____.

DETAILED ACTION

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

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 11 June 2013 has been considered by the examiner.

Specification

3. The disclosure is objected to because of the following informalities:

4. An updated status of the parent nonprovisional application should be included in the first sentence of the specification. A statement reading "…Serial No. 13/329,770, filed December 19, 2011, **which issued as U.S. Patent No. 8,481,046** …" should be entered. Appropriate correction is suggested.

Double Patenting

5. 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 obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

6. 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 conflicting 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.

7. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-16 and 19 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 8,092,803. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the ophthalmic formulation of the VEGF antagonist recited in the instant claims is overlapping in scope with the ophthalmic formulation of VEGF antagonist recited in claims 1-19 of U.S. Patent No. 8,092,803. While the claims in '803 patent recite that the VEGF antagonist comprises amino acids 27-475 of SEQ ID NO:4, and not amino acids 27-457 of SEQ ID NO:4 as recited in instant claims 1-16 and 19, it is noted that this species of VEGF antagonist is a specific preferred embodiment of VEGF antagonist (See column 5). Moreover, it is noted it is noted that a VEGF antagonist *comprising* amino acids 27-475 of SEQ ID NO:4 is encompassed by a VEGF antagonist comprising amino acids 27-475 of SEQ ID NO:4 of the '803 patent. Lastly, while the claims in '803 patent do not recite a dimeric VEGF antagonist comprising two of the fusion polypeptides recited in the claims, it would have been obvious to a person of ordinary skill in the art to utilize a dimeric form of the VEGF antagonist recited in the claims of the '803 patent. The motivation to do so is found in the '803 patent, which discloses dimeric fusion polypeptides as a

preferred embodiment of the fusion polypeptide (See column 2). Therefore, the claims are overlapping in scope.

9. Claims 1-16 and 19 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 7,608,261. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the ophthalmic formulation of the VEGF antagonist recited in the instant claims is overlapping in scope with the ophthalmic formulation of VEGF antagonist recited in claims 1-17 of U.S. Patent No. 7,608,261. While the claims in '261 patent recite that the VEGF antagonist comprises the amino acid sequence of SEQ ID NO:4, and not amino acids 27-457 of SEQ ID NO:4 as recited in instant claims 1-16 and 19, it is noted that this species of VEGF antagonist is a specific preferred embodiment of VEGF antagonist (See column 5). Moreover, it is noted it is noted that a VEGF antagonist *comprising* amino acids 27-475 of SEQ ID NO:4 is encompassed by a VEGF antagonist comprising the amino acid sequence of SEQ ID NO:4 of the '261 patent. Lastly, while the claims in '261 patent do not recite a dimeric VEGF antagonist comprising two of the fusion polypeptides recited in the claims, it would have been obvious to a person of ordinary skill in the art to utilize a dimeric form of the VEGF antagonist recited in the claims of the '261 patent. The motivation to do so is found in the '261 patent, which discloses dimeric fusion polypeptides as a preferred embodiment of the fusion polypeptide (See column 2). Therefore, the claims are overlapping in scope.

10. Claims 1-16 and 19 are rejected on the ground of nonstatutory obviousness-type double

patenting as being unpatentable over claims 1-2 of U.S. Patent No. 7,531,173 in view of Dix et al. (WO 2006/104852; cited by Applicant).

11. The claims of the '173 patent are drawn to an ophthalmic composition comprising a VEGF antagonist in a pharmaceutically acceptable carrier, wherein the VEGF antagonist is VEGFR1R2-FcΔC1(a) polypeptide. It is noted that VEGFR1R2-FcΔC1(a) polypeptide recited in the claims of the '173 patent, which the Specification identifies as having the amino acid sequence set forth in SEQ ID NO:2 (See column 1), shares 100% sequence identity with SEQ ID NO:4 of the instant Application. While the claims in '173 patent do not recite a dimeric VEGF antagonist comprising two of the fusion polypeptides recited in the claims, it would have been obvious to a person of ordinary skill in the art to utilize a dimeric form of the VEGF antagonist recited in the claims of the '173 patent. The motivation to do so is found in the '173 patent, which discloses dimeric fusion polypeptides as a preferred embodiment of the fusion polypeptide (See column 5). The claims in '173 patent do not recite do not recite (a) a particular concentration of the VEGFR1R2-FcΔC1(a) polypeptide, (b) phosphate buffer, (c) a tonicity agent selected from sodium chloride or potassium chloride, (d) a stabilizing agent selected from the group consisting of sucrose, sorbitol, glycerol, trehalose, or mannitol, (e) an organic co-solvent(s) such as polysorbate, PEG, or propylene glycol, or (f) having a particular pH.

12. Dix et al. (WO 2006/104852; cited by Applicant) teach stable liquid and pre-lyophilized (i.e., lyophilizable) pharmaceutical formulations comprising a VEGFR1R2 fusion protein, including the VEGFR1R2-FcΔC1(a) polypeptide. Dix et al. also teach said compositions comprising (a) VEGFR1R2-FcΔC1(a) polypeptide at varying concentrations, including 25, 10-50, 5-75, 12.5-75, and 50-100 mg/ml (See pg. 1[0006] and pg. 2[0007], [0009], and [0010]), (b)

5 mM and 1-10 mM phosphate buffer (See pg. 1[0006]), (c) 50 mM, 100 mM, or 25-150 mM sodium chloride (See pg. 1[0006] and pg. 2[0007]), (d) 0.5-6%, 2.5%, 5-20%, and 5-30% sucrose (See pg. 2[0006], [0007], [0009], and [0010], (e) 0.05-0.15% and 0.1-0.5% polysorbate, or 1-5% PEG, and (f) having a pH of 6-6.5 (See pg. 2[0006]). Lastly, Dix et al. also disclose a pre-filled syringe comprising said pharmaceutical formulation (See pg. 11[0047]).

13. Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to have used the teachings of Dix et al. to obtain ophthalmic formulations suggested in the '173 patent. The person of ordinary skill in the art would have been motivated to do so since the '173 patent discloses that the claimed VEGFR1R2 fusion protein formulations are useful for treating eye disorders, and the formulations comprising the VEGFR1R2 fusion protein taught by the Dix et al. reference have increased stability. The expectation of success is high since the claimed VEGFR1R2 fusion protein in the '173 patent is identical to the VEGFR1R2 fusion proteins disclosed in the Dix et al. reference. Moreover, the exact values for the concentrations of the various components of the composition are part of routine optimization in the art. Furthermore, as for the specific amounts/concentrations used, it is noted that it is customary and routine to optimize dosages and ratios of the agents according to the type of dysfunction, and the severity and course of the disease.

14. Claims 17 and 18 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 7,807,164. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the ophthalmic formulation of the VEGF antagonist recited in the instant claims is

overlapping in scope with the ophthalmic formulation of VEGF antagonist recited in claims 1-9 of U.S. Patent No. 7,807,164. While the claims in '164 patent recite that the VEGF antagonist comprises the amino acid sequence of SEQ ID NO:4, and not amino acids 27-457 of SEQ ID NO:4 as recited in instant claims 17 and 18, it is noted that this species of VEGF antagonist is a specific preferred embodiment of VEGF antagonist (See column 6). Moreover, it is noted it is noted that a VEGF antagonist *comprising* amino acids 27-475 of SEQ ID NO:4 is encompassed by a VEGF antagonist comprising the amino acid sequence of SEQ ID NO:4 of the '164 patent. Lastly, while the claims in '164 patent do not recite a dimeric VEGF antagonist comprising two of the fusion polypeptides recited in the claims, it would have been obvious to a person of ordinary skill in the art to produce a dimeric form of the VEGF antagonist recited in the claims of the '164 patent. The motivation to do so is found in the '164 patent, which discloses dimeric fusion polypeptides as a preferred embodiment of the fusion polypeptide (See column 2). Therefore, the claims are overlapping in scope.

15. Claims 17 and 18 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 8,481,046. While the claims in '046 patent do not recite a dimeric fusion polypeptide comprising two of the fusion polypeptides recited in the claims, it would have been obvious to a person of ordinary skill in the art to produce a dimeric form of the VEGF antagonist recited in the claims of the '046 patent. The motivation to do so is found in the '046 patent, which discloses dimeric fusion polypeptides as a preferred embodiment of the fusion polypeptide (See column 2).

Summary

15. No claim is allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jon M. Lockard** whose telephone number is **(571) 272-2717**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joanne Hama**, can be reached on **(571) 272-2911**. The fax 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.

/JON M LOCKARD/
Examiner, Art Unit 1647
October 4, 2013