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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/329,770	07/09/2013	8481046	5050D	6336

26693 7590 06/19/2013
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):

Eric FURFINE, Concord, MA;
Daniel Dix, LaGrangeville, NY;
Kenneth S. Graham, Pleasant Valley, NY;
Kelly Frye, Mendham, NJ;

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NOTICE OF ALLOWANCE AND FEE(S) DUE

26693 7590 03/20/2013
REGENERON PHARMACEUTICALS, INC
777 OLD SAW MILL RIVER ROAD
TARRYTOWN, NY 10591

EXAMINER

LOCKARD, JON MCCLELLAND

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 03/20/2013

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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13/329,770

12/19/2011

INV001Eric FURFINE

5050D

6336

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	\$1780	\$300	\$0	\$2080	06/20/2013

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
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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)

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.

26693 7590 03/20/2013
REGENERON PHARMACEUTICALS, INC
777 OLD SAW MILL RIVER ROAD
TARRYTOWN, NY 10591

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.
13/329,770	12/19/2011	INV001Eric FURFINE	5050D	6336

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	\$1780	\$300	\$0	\$2080	06/20/2013

EXAMINER	ART UNIT	CLASS-SUBCLASS
LOCKARD, JON MCCLELLAND	1647	424-134100

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 credit 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 form 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: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____

This collection of information 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.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/329,770	12/19/2011	INV001Eric FURFINE	5050D	6336

26693 7590 03/20/2013
REGENERON PHARMACEUTICALS, INC
777 OLD SAW MILL RIVER ROAD
TARRYTOWN, NY 10591

EXAMINER

LOCKARD, JON MCCLELLAND

ART UNIT PAPER NUMBER

1647

DATE MAILED: 03/20/2013

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

The Patent Term Adjustment to date is 0 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 0 day(s).

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 Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

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.

<i>Examiner-Initiated Interview Summary</i>	Application No. 13/329,770	Applicant(s) FURFINE ET AL.	
	Examiner JON M. LOCKARD	Art Unit 1647	

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

(1) JON M. LOCKARD. (3) ____.

(2) JOSEPH E. ZAHNER. (4) ____.

Date of Interview: 27 February 2013.

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: 22,27 and 34-42.

Identification of prior art discussed: N/A.

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...)

The Examiner proposed amending claims 22 and 27, and cancelling newly added claims 34-42 to place the application in condition for allowance. An agreement was reached.

Applicant recordation instructions: It is not necessary for applicant to provide a separate record of the substance of 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

/JON M LOCKARD/ Examiner, Art Unit 1647	
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Notice of Allowability	Application No.	Applicant(s)	
	13/329,770	FURFINE ET AL.	
	Examiner	Art Unit	
	JON M. LOCKARD	1647	

-- 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 25 January 2013.
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 22,23 and 27-33 (renumbered as claims 1,5,2-4 and 6-9, 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).
 - 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) | 5. ☒ Examiner's Amendment/Comment |
| 2. ☐ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date ____ | 6. ☐ Examiner's Statement of Reasons for Allowance |
| 3. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 7. ☐ Other ____. |
| 4. ☒ Interview Summary (PTO-413),
Paper No./Mail Date <u>20130227</u> . | |

/J. M. L./
Examiner, Art Unit 1647

/Christine J Saoud/
Primary Examiner, Art Unit 1647

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Joseph Zahner on 27 February 2013.

The application has been amended as follows:

2. Claims 34-42 have been cancelled without prejudice or disclaimer.
3. In claim 22, part (a), the phrase "comprising the amino" has been deleted, and the phrase --comprising amino-- inserted therefor.
4. In claim 27, the phrase "sucrose, pH about" has been deleted, and the phrase --sucrose, wherein the pH is about-- inserted therefor.

Art Unit: 1647

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
February 27, 2013

/Christine J Saoud/
Primary Examiner, Art Unit 1647

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent Application of: Eric FURFINE

Confirmation No.: 6336

Application No.: 13/329,770

Art Unit: 1647

Filed: 12/19/2011

Examiner: Jon LOCKARD

For: VEGF Antagonist Formulations for Intravitreal Administration

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

AMENDMENT AND RESPONSE UNDER 37 CFR § 1.111

Applicants file this amendment and remarks in reply to the non-final office action mailed on 09/27/2012, and respectfully request that the Office reconsider the claims for patent. Since this paper is filed within the first month past the three-month shortened statutory period, Applicants request a one-month extension of time. The Commissioner is authorized to deduct the required extension-of-time fee of \$150 from deposit account number 18-0650.

Amendments to the specification begin on page 2.

Amendments to the claims begin on page 3.

Remarks begin on page 5.

IN THE SPECIFICATION

Applicants replace paragraph [0001] on page 1 of the specification with the following marked-up version of paragraph [0001].

[0001] This application is a continuation of U.S. Patent Application Serial No. 12/833,417, filed 9 July 2010, which issued as U.S. Patent No. 8,092,803 on 10 January 2012, which is a continuation of U.S. Patent Application Serial No. 12/560,885, filed 16 September 2009, which issued as U.S. Patent No. 7,807,164 ~~7,8107,164~~ on 5 October 2010, which is a divisional application of U.S. Patent Application Serial No. 11/818,463, filed 14 June 2007, which issued as U.S. Patent No. 7,608,261 on 27 October 2009, which claims the benefit under 35 U.S.C. § 119(e) of U.S. Provisional Application No.: 60/814,484, filed 16 June 2006, which applications are each hereby incorporated by reference.

IN THE CLAIMS

The following listing of the claims replaces all prior versions of the listing of the claims.

1. – 21. (canceled)

22. (currently amended) A method of producing a lyophilized formulation of a VEGF antagonist, comprising ~~the step of subjecting the pre-lyophilized formulation of claim 13 to lyophilization a~~ prelyophilization formulation, 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.

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

(a) 5-50 mg/ml of 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.

24. – 26. (canceled)

27. (new) The method of claim 22, 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.

28. (new) The method of claim 22, 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.

29. (new) The method of claim 22, 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.

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

31. (new) The method of claim 23, wherein the organic co-solvent is polysorbate at 0.015%.

32. (new) The method of claim 23, 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.

33. (new) The method of claim 23, wherein the sodium phosphate buffer is at 5 mM.

34. (new) A lyophilized formulation made according to the method of claim 22.

35. (new) The lyophilized formulation of claim 34, 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.

36. (new) The lyophilized formulation of claim 34, 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.

37. (new) The lyophilized formulation of claim 34, 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.

38. (new) A lyophilized formulation made according to the method of claim 23.

39. (new) The lyophilized formulation of claim 38, wherein the tonicity agent is sodium chloride at a concentration selected from the group consisting of 20 mM and 67.5 mM.

40. (new) The lyophilized formulation of claim 38, wherein the organic co-solvent is polysorbate at 0.015%.

41. (new) The lyophilized formulation of claim 38, 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.

42. (new) The lyophilized formulation of claim 38, wherein the sodium phosphate buffer is at 5 mM.

REMARKSObjection to the specification

The Office objects to the parent case text section of the specification, requiring Applicants to indicate that parent application 12/833,417 had granted on January 10, 2012 as US Patent No. 8,092,803. Applicants have done so and therefore request removal of the objection.

Double patenting rejection

The Office rejects claims 1-21 and 24-26 under the judicially created doctrine of obviousness-type double patenting in view of commonly owned patents number 8,092,803 and 7,608,261. The Office also declares that claims 22 and 23 as “allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.” (Office Action, pg. 4, ¶ 10.)

In the interest of promoting prosecution, Applicants currently cancel claims 1-21 and 24-26 without disclaimer or prejudice, reserving the right to pursue the subject matter of those claims in this or another patent application.

At the Office’s suggestion, Applicants currently amend claims 22 and 23 to incorporate all of the elements of claims 13 and 17 respectively. Furthermore, new claims 27-29 and 30-33 are presented, which incorporate the subject matter of claims 14-16 and 18-21, which were dependent upon claims 13 and 17. Finally, new claims 34-37 are presented, which correspond to the product by the processes of claims 22 and 27-29; and new claims 38-42, which correspond to the product by the process of claims 23 and 30-33. No new matter is presented. The amendments incorporate the subject matter of previously presented claims.

Conclusion

In view of the amendments, Applicants believe that the claims are allowable. Applicants therefore respectfully request that the Office issue a notice of allowance. The Examiner is invited to call Undersigned if any other issues remain.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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13/329,770

12/19/2011

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26693 7590 09/27/2012
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EXAMINER

LOCKARD, JON MCCLELLAND

ART UNIT

PAPER NUMBER

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MAIL DATE

DELIVERY MODE

09/27/2012

PAPER

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. 13/329,770	Applicant(s) FURFINE ET AL.	
	Examiner JON M. LOCKARD	Art Unit 1647	

-- 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 19 December 2011.
- 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) 1-26 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) 1-21 and 24-26 is/are rejected.
- 8) ☒ Claim(s) 22 and 23 is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

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).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
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) | 4) ☐ Interview Summary (PTO-413) |
| 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) ☒ Information Disclosure Statement(s) (PTO/SB/08) | 5) ☐ Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/19/11</u> . | 6) ☐ Other: ____. |

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on 19 December 2011 has been considered by the examiner.

Specification

2. The disclosure is objected to because of the following informalities:
3. An updated status of the parent nonprovisional application should be included in the first sentence of the specification. A statement reading "...Serial No. 12/833,417, filed 9 July 2010, **which issued as U.S. Patent No. 8,092,803** ..." should be entered. Appropriate correction is suggested.

Double Patenting

4. 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).
5. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may

Art Unit: 1647

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.

6. 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).

7. Claims 1-21 and 24-26 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 2-26, it is noted that this species of VEGF antagonist is a specific preferred embodiment of VEGF antagonist (See column 5). Moreover, 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. Therefore, the claims are overlapping in scope.

8. Claims 1-21 and 24-26 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

Art Unit: 1647

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 2-26, 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. Therefore, the claims are overlapping in scope.

Summary

9. Claims 1-21 and 24-26 stand rejected.
10. Claims 22 and 23 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Art Unit: 1647

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, **Ram Shukla**, can be reached on **(571) 272-0735**. 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
September 26, 2012

13/329,770

/JML/

* * * * * STN Columbus * * * * *

=> DIS HIST

(FILE 'HOME' ENTERED AT 17:01:06 ON 26 SEP 2012)

FILE 'MEDLINE, SCISEARCH, EMBASE, BIOSIS' ENTERED AT 17:01:25 ON 26 SEP 2012

L1	3354 S VEGF (S) (ANTAGONIST OR TRAP)
L2	84 S L1 AND OPHTHALMIC
L3	60 S L1 AND (COMPOSITION OR FORMULATION)
L4	11 S L2 AND L3
L5	11 DUP REM L4 (0 DUPLICATES REMOVED)