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.
14/330,096	05/17/2016	9340594	5050CON4	2013

138357 7590 04/27/2016
Kutak Rock LLP
2300 Main Street, Suite 800
Kansas City, MO 64108

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;
Regeneron Pharmaceuticals, Inc., Tarrytown, NY;
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.

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NOTICE OF ALLOWANCE AND FEE(S) DUE

138357 7590 03/02/2016
Kutak Rock LLP
2300 Main Street, Suite 800
Kansas City, MO 64108

EXAMINER
LOCKARD, JON MCCLELLAND

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 03/02/2016

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/330,096	07/14/2014	Eric FURFINE	5050CON4	2013

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	06/02/2016

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)

138357 7590 03/02/2016
Kutak Rock LLP
2300 Main Street, Suite 800
Kansas City, MO 64108

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

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

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/330,096	07/14/2014	Eric FURFINE	5050CON4	2013

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nonprovisional	UNDISCOUNTED	$960	$0	$0	$960	06/02/2016

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,
(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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14/330,096	07/14/2014	Eric FURFINE	5050CON4	2013

138357 7590 03/02/2016
Kutak Rock LLP
2300 Main Street, Suite 800
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EXAMINER
LOCKARD, JON MCCLELLAND

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 03/02/2016

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

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

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

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

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

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

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

Privacy Act Statement

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

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

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

Notice of Allowability	Application No. 14/330,096	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 After-Final Amendment filed 15 February 2016*.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on_____.
2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
3. ☒ The allowed claim(s) is/are *1,3,5-7 and 9-15 (renumbered as claims 1,3-5,8-10,2,6,11,7 and 12, 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

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14330096	FURFINE ET AL.
	Examiner	**Art Unit**
	JON M LOCKARD	1647

CPC						
Symbol					**Type**	**Version**
C07K		14	/	47	F	2013-01-01
A61K		9	/	0048	I	2013-01-01
A61K		9	/	19	I	2013-01-01
A61K		38	/	1793	I	2013-01-01
C07K		2319	/	30	A	2013-01-01
C07K		14	/	4705	I	2013-01-01
A61M		5	/	178	I	2013-01-01
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CPC Combination Sets								
Symbol					**Type**	**Set**	**Ranking**	**Version**
			/					
			/					

/JON M LOCKARD/ Examiner.Art Unit 1647 (Assistant Examiner)	02/18/2016 (Date)	**Total Claims Allowed:** 12	
/CHRISTINE J SAOUD/ Primary Examiner.Art Unit 1647 (Primary Examiner)	02/21/2016 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure NONE

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	14330096	FURFINE ET AL.
	Examiner	**Art Unit**
	JON M LOCKARD	1647

US ORIGINAL CLASSIFICATION	
CLASS	**SUBCLASS**
424	134.1

CROSS REFERENCE(S)

CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)				
424	192.1				
514	1.1	8.1			
530	350				

INTERNATIONAL CLASSIFICATION

CLAIMED					NON-CLAIMED				
A	6	1	K	38 / 18 (2006.01.01)					
C	0	7	K	14 / 71 (2006.01.01)					

/JON M LOCKARD/ Examiner.Art Unit 1647 (Assistant Examiner)	02/18/2016 (Date)	**Total Claims Allowed:** 12	
/CHRISTINE J SAOUD/ Primary Examiner.Art Unit 1647 (Primary Examiner)	02/21/2016 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure NONE

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14330096	FURFINE ET AL.
	Examiner	**Art Unit**
	JON M LOCKARD	1647

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

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
1	1														
3	3														
4	5														
5	6														
8	7														
9	9														
10	10														
2	11														
6	12														
11	13														
7	14														
12	15														

/JON M LOCKARD/ Examiner.Art Unit 1647 (Assistant Examiner)	02/18/2016 (Date)	**Total Claims Allowed:** 12	
/CHRISTINE J SAOUD/ Primary Examiner.Art Unit 1647 (Primary Examiner)	02/21/2016 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure NONE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: **14/330,096**	Examiner: **Lockard, Jon McClelland**
Applicant: **FURFINE, Eric**	Group Art Unit: **1647**
Filed: **July 14, 2014**	Confirmation No.:**2013**
Title: **VEGF Antagonist Formulations for Intravitreal Administration**	Customer No.: **138357**
	Docket No.: **238811-16.12**

February 15, 2016

Filed Electronically Via EFS-WEB

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

RESPONSE TO FINAL OFFICE ACTION UNDER 37 CFR §1.116

Dear Sirs:

Applicants submit the following remarks and terminal disclaimer in response to the Final Office Action mailed on November 20, 2015 and due for reply on February 20, 2015. Since this reply is submitted within the shortened statutory period for reply, Applicants believe that no extensions of time or concomitant fees are due. The Commissioner is authorized to deduct the $160 terminal disclaimer fee under §1.20(d), and to charge any deficiency or credit any overpayment with respect to this submission to deposit account number 50-4104.

Remarks begin on page 2.

Remarks

Status of the Claims

Claims 1, 3, 5-7, and 9-15 are pending. Claims 2, 4 and 8 are canceled. Claims 1, 3, 5-7, 9-11, 14, and 15 stand rejected on the ground of nonstatutory obviousness-type double patenting. Claims 12 and 13 are objected to as being dependent upon a rejected base claim, but otherwise allowable if written in independent form.

Withdrawn Objections and Rejections

The Applicants wish to thank the Examiner for withdrawing the objection to the specification, the rejection of claims 1-4, 7 and 8 under §112, first paragraph, and the rejection of claims 1-10 on the ground of nonstatutory obviousness-type double patenting.

New Rejection on the Ground of Non-Statutory Obviousness Double Patenting

The Office rejects claims 1, 3, 5-7, 9-11, 14 and 15 on the ground of non-statutory double patenting as being unpatentable over claims 1-15 of co-owned U.S. Patent No. 7,608,261 and over claims 1-7 and 17 of U.S. Patent No. 8,092,803. Solely in the interest of promoting prosecution and reserving the right to pursue the subject matter in another application, Applicants herein terminally disclaim any term of the patent that grants from this application beyond the term of U.S. Patents No. 7,608,261 and 8,092,803. A terminal disclaimer is filed herewith.

Conclusion

As it is believed the application is in condition for allowance, a prompt and favorable consideration of the application and Notice of Allowance are respectfully requested. If any further fees are required in connection with the filing of this amendment, please charge the same to our Deposit Account No. 50-4104.

Respectfully Submitted,

Kutak Rock LLP
Customer Number: 138357

By: /Joseph E. Zahner, Reg. No. 48,224/
Joseph E. Zahner
Reg. No. 48,224
Telephone No. 816-502-4663

ATTORNEYS FOR APPLICANT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: **14/330,096**	Examiner: **Lockard, Jon McClelland**
Applicant: **FURFINE, Eric**	Group Art Unit: **1647**
Filed: **July 14, 2014**	Confirmation No.:**2013**
Title: **VEGF Antagonist Formulations for Intravitreal Administration**	Customer No.: **138357**
	Docket No.: **238811-16.12**

February 15, 2016

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Commissioner for Patents
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Alexandria, VA 22313-1450

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The Applicants wish to thank the Examiner for withdrawing the objection to the specification, the rejection of claims 1-4, 7 and 8 under §112, first paragraph, and the rejection of claims 1-10 on the ground of nonstatutory obviousness-type double patenting.

New Rejection on the Ground of Non-Statutory Obviousness Double Patenting

The Office rejects claims 1, 3, 5-7, 9-11, 14 and 15 on the ground of non-statutory double patenting as being unpatentable over claims 1-15 of co-owned U.S. Patent No. 7,608,261 and over claims 1-7 and 17 of U.S. Patent No. 8,092,803. Solely in the interest of promoting prosecution and reserving the right to pursue the subject matter in another application, Applicants herein terminally disclaim any term of the patent that grants from this application beyond the term of U.S. Patents No. 7,608,261 and 8,092,803. A terminal disclaimer is filed herewith.

Conclusion

As it is believed the application is in condition for allowance, a prompt and favorable consideration of the application and Notice of Allowance are respectfully requested. If any further fees are required in connection with the filing of this amendment, please charge the same to our Deposit Account No. 50-4104.

Respectfully Submitted,

Kutak Rock LLP
Customer Number: 138357

By: /Joseph E. Zahner, Reg. No. 48,224/
Joseph E. Zahner
Reg. No. 48,224
Telephone No. 816-502-4663

ATTORNEYS FOR APPLICANT

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/330,096	07/14/2014	Eric FURFINE	5050CON4	2013

26693 7590 11/20/2015
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
11/20/2015	ELECTRONIC

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

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

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

patents@regeneron.com

Office Action Summary	Application No. 14/330,096	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 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

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

Status

1)☒ Responsive to communication(s) filed on *02 September 2015*.

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

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

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

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

Disposition of Claims*

5)☒ Claim(s) *1,3,5-7 and 9-15* is/are pending in the application.

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

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1,3,5-7,9-11,14 and 15* is/are rejected.

8)☒ Claim(s) *12 and 13* is/are objected to.

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

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

Application Papers

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

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

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

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

Priority under 35 U.S.C. § 119

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

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

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

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

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

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

Attachment(s)

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

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

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

4) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments, and/or Claims

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

2. The Amendment filed 02 September 2015 has been received and entered in full. Claims 1, 3, 5-7, 9, and 10 have been amended, claims 2, 4, and 8 have been cancelled, and claims 11-15 have been added. Newly added claims 11-15 will be examined as they fit under the rubric of the elected invention. Therefore, claims 1, 3, 5-7, and 9-15 are pending and the subject of this Office Action.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objections and/or Rejections

4. The objection to the specification as set forth at pg. 2 of the previous Office action (mailed 02 April 2015) is withdrawn in view of Applicant's amendment to the specification (filed 02 September 2015).

5. The rejection of claims 1-4, 7, and 8 under 35 U.S.C. 112, 1st paragraph as set forth at pp. 2-5 of the previous Office action (mailed 02 April 2015) is withdrawn in view of Applicant's amendment of claims 3 and 7, and cancellation of claims 2, 4, and 8 (filed 02 September 2015).

6. The rejection of claims 1-10 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 of U.S. Pat. No. 7,531,173 in view of Dix et al (WO 2006/104852) as set forth at pp. 7-8 of the previous Office action (mailed 02 April 2015) is withdrawn in view of Applicant's amendment of claims 3 and 7, and cancellation of claims 2, 4, and 8 (filed 02 September 2015).

Maintained and/or New Objections and/or Rejections

Double Patenting

7. 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).

8. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the reference application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

9. The USPTO internet Web site contains terminal disclaimer forms which may be used. Please visit http://www.uspto.gov/forms/. The filing date of the application will determine what form should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to http://www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

10. Claims 1, 3, 5-7, 9 and 10 remain rejected, and newly added claims 11, 14, and 15 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable

over claims 1-7 and 17 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 1-7 and 17 of U.S. Patent No. 8,092,803. The claims in the '803 patent also recite a pre-filled syringe comprising the ophthalmic composition comprising the VEGF antagonist (See claims 10-15). While the claims in the '803 patent do not recite that the syringe is a 1 ml glass syringe with a plunger, this is the only embodiment of a syringe defined in the specification (See Examples 4 and 6 at Columns 9 and 10, respectively). Therefore, the claims are overlapping in scope.

11. Claims 1, 3, 5-7, 9 and 10 remain rejected, and newly added claims 11, 14, and 15 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 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 1-15 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 the instant claims, it is noted that this species of VEGF antagonist is a specific preferred embodiment of VEGF antagonist (See column 5). The claims in the '261 patent also recite a pre-filled syringe comprising the ophthalmic composition comprising the VEGF antagonist (See claim 17). While the claims in the '261 patent do not recite that the syringe is a 1 ml glass syringe with a plunger, this is the only

embodiment of a syringe defined in the specification (See Examples 4 and 6 at Columns 9 and 10, respectively). Therefore, the claims are overlapping in scope.

Summary

12. Claims 1, 3, 5-7, 9-11, 14 and 15 are rejected.

13. Claims 12 and 13 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.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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

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
November 10, 2015

/Christine J Saoud/
Primary Examiner, Art Unit 1647

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent App. of: Regeneron Pharmaceuticals Inc.	Confirmation No.: 2013
Application No.: 14/330,096	Art Unit: 1647
Filed: July 14, 2014	Examiner: LOCKARD, Jon McClelland
For: VEGF Antagonist Formulations for Intravitreal Administration	

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

REPLY TO OFFICE ACTION UNDER 37 CFR §1.111

Applicants submit the following amendment and remarks in response to the Non-final Office Action mailed on April 2, 2015 and due for reply on July 2, 2015. Since this reply is submitted within two months past the shortened statutory period for reply, Applicants petition the Commissioner for a two-month extension of time under §1.136(a). The Commissioner is authorized to deduct the $600 extension of time fee under §1.17(a)(2) from deposit account numbered 18-0650.

Applicants kindly request the Office to enter the following amendments into the application and to favorably consider the remarks and amendments.

Amendments to the specification begin on page 2.

Amendments to the claims begin on page 3.

Remarks begin on page 5.

IN THE SPECIFICATION

The following marked-up paragraph replaces the first paragraph on page 1 of the specification-as-filed.

[0001] This application is a continuation application of U.S. patent application Ser. No. 13/914,996, filed Jun. 11, 2013, which issued as U.S. Pat. No. 8,802,107 on Aug. 12, 2014, which is a continuation application of U.S. patent application Ser. No. 13/329,770, filed Dec. 19, 2011, which issued as U.S. Pat. No. 8,481,046 on Jul. 9, 2013, 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.

IN THE CLAIMS

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

1. (currently amended) A pre-filled syringe suitable for intravitreal administration comprising a 1 mL luer glass syringe fitted with a plunger and a stable ophthalmic formulation of a vascular endothelial growth factor (VEGF) trap ~~antagonist~~, which consists of (i) a receptor component consisting essentially of an immunoglobulin-like domain 2 of a first VEGF receptor and an immunoglobulin-like domain 3 of a second VEGF receptor, and (ii) a multimerizing component, wherein the stable ophthalmic formulation comprises:

(a) 1-100 mg/ml a VEGF antagonist;

(b) 0.01-5% of one or more organic co-solvent;

(c) 5-40 mM of buffer; and

(d) optionally comprising 1.0-7.5% of a stabilizing agent.

2. (canceled)

3. (currently amended) The pre-filled syringe according to claim [2] 11, wherein the VEGF trap ~~antagonist~~ is stable for at least 4 months.

4. (canceled)

5. (currently amended) The pre-filled syringe according to claim [4] 3, wherein the VEGF trap ~~VEGF- specific fusion protein comprises~~ consists of amino acids 27-457 of SEQ ID NO:4.

6. (currently amended) The pre-filled syringe according to claim 5, wherein the stable ophthalmic formulation comprises 40 mg/mL of the VEGF trap ~~VEGF- specific fusion protein~~, 10 mM phosphate, 40 mM NaCl, 0.03% polysorbate 20, 5% sucrose, at pH 6.2-6.4.

7. (currently amended) The pre-filled syringe according to claim [2] 11, wherein the VEGF trap ~~antagonist~~ is stable for at least 5 months.

8. (canceled)

9. (currently amended) The pre-filled syringe according to claim [8] 7, wherein the VEGF trap ~~VEGF- specific fusion protein comprises~~ consists of amino acids 27-457 of SEQ ID NO:4.

10. (currently amended) The pre-filled syringe according to claim 9, wherein the stable ophthalmic formulation comprises 40 mg/mL of the VEGF trap ~~VEGF- specific fusion protein~~, 10 mM phosphate, 135 mM NaCl, and 0.03% polysorbate 20, at pH 6.2-6.4.

11. (new) The pre-filled syringe of claim 1, wherein the first VEGF receptor is Flt1, and the second VEGF receptor is Flk1 or Flt4.

12. (new) The pre-filled syringe of claim 3, wherein the VEGF trap consists of the amino acid sequence of SEQ ID NO:2.

13. (new) The pre-filled syringe of claim 7, wherein the VEGF trap consists of the amino acid sequence of SEQ ID NO:2.

14. (new) The pre-filled syringe of claim 3, wherein the VEGF trap consists of the amino acid sequence of SEQ ID NO:4.

15. (new) The pre-filled syringe of claim 7, wherein the VEGF trap consists of the amino acid sequence of SEQ ID NO:4.

REMARKS

Status of the Claims

Claims 1-10 were pending at the time of this Office action. Claims 1-10 were rejected on the grounds of nonstatutory obviousness-type double patenting. Claims 1-4, 7 and 8 were rejected under 35 USC §112(a), written description.

Applicants have currently canceled claims 2, 4 and 8 without prejudice or disclaimer. Applicants have currently amended claim 1 by replacing the phrase "VEGF antagonist" with the phrase "VEGF trap, which *consists of* a receptor component consisting essentially of an immunoglobulin-like domain 2 of a first VEGF receptor and immunoglobulin-like domain 3 of a second VEGF receptor, and a multimerizing component." Support for this amendment is described at paragraph 0003 and described in Kim *et al.,* 2002 and Holash *et al.,* 2002, which are incorporated in their entireties by reference in the instant specification (paragraph 0003), and described at paragraph 0007. No new matter is presented by this amendment. Claim 1 is also amended to include the subject matter of claim 2.

Applicants have amended claims 3, 5-7, 9 and 10 to update references to "the VEGF-specific fusion protein" in those claims to "the VEGF trap" to preserve the antecedence of claim 1. No new matter is presented by this amendment. Claims 5 and 9 are currently amended to limit the VEGF trap to the amino acid sequence *consisting of* amino acids 27-457 of SEQ ID NO:4, as opposed to *comprising* amino acids 27-457 of SEQ ID NO:4. This amendment does not present new matter.

New claims 11-15 are presented, which are directed to various embodiments of the VEGF trap described in the specification as filed. Claims 12 and 13 are directed to a VEGF trap consisting of the sequence of SEQ ID NO:2, and claims 14 and 15 are directed to a VEGF trap consisting of the sequence of SEQ ID NO:4. Support for these additional claims is described at paragraph 0007; no new matter is presented.

Rejection under 35 USC §112(a), written description

The Office rejected claims 1-4, 7 and 8 under §112, first paragraph (pre-AIA) or §112(a) for allegedly lacking written description. The Office essentially alleged that the claim element "VEGF antagonist" is a "functional property" that encompasses any "compound capable of blocking or inhibiting the biological action of vascular endothelial growth factor", and that "there does not appear to be an adequate written description in the specification as filed of all VEGF antagonists," (Office action at p.3, para. 9).

In the interest of promoting prosecution, Applicants have amended claim 1 (from which all other claims depend) to include a structural description of the VEGF antagonist, fully supported by the original written description. Namely, the VEGF antagonist is limited to a VEGF trap, which is structurally described at paragraphs [0003], [0007], and [0046]. Furthermore, new claims 11-15 are limited to specific structural embodiments of the VEGF trap described at paragraph [0007].

In view of these amendments restricting the claims to structural embodiments of the VEGF antagonist that are particularly described in the specification as filed, Applicants respectfully ask the Office to withdraw its rejection of the claims under §112(a), written description.

Nonstatutory double patenting rejection

The Office rejected claims 1-10 under the judicially created doctrine of obviousness-type double patenting. The Office separately alleges that the pending claims were unpatentable (1) over claims 1-7 and 17 of US Patent No. 8,092,803 ("'803 patent"), (2) over claims 1-15 of US Patent No. 7,608,261 ("'261 patent"), and (3) over claims 1 and 2 of US Patent No. 7,531,173 ("'173 patent") in view of Dix *et al.,* (WO 2006/104852) given the alleged overlapping subject matter between the claims.

Applicants have amended claim 1 to include (in addition to the stable ophthalmic formulation containing the VEGF trap) the element of a 1 mL luer glass syringe fitted with a plunger. Also, claims 1, 5 and 9 are currently amended to limit the VEGF trap to a molecule *consisting of* specific amino acid sequences (*i.e.,* amino acids 27-457 of SEQ ID NO:4 for claim 5

and 9) or specific molecular elements (*i.e.,* receptor and multimerizing [*i.e.,* Fc domain] components for claim 1).

None of the claims cited by the Office against the instant case specifically include the specific 1 mL luer glass syringe fitted with a plunger as a claim element, nor the specific limited molecular structures, nor the combination of both specific elements. Therefore, the amended claims are patentably distinct from claims 1-15 of the '803 patent, claims 1-7 and 17 of the '261 patent, and claims 1 and 2 of the '173 patent. In view of the amendments to the instant claims, Applicants believe that the claims are patentably and therefore respectfully ask the Office to withdraw its rejection of the claims on the grounds of nonstatutory obiviousness-type double patenting.

CONCLUSION

Applicants respectfully request the Office to reconsider the claims in view of the remarks and the amendments made to the specification and the claims; to withdraw the rejections to the claims under §112(a) and nonstatutory obviousness-type double patenting; and to issue a notice of allowance. If any other issue remains in this case, the Examiner is invited to call Undersigned Attorney for the Applicants.

Respectfully submitted

/Joseph E. Zahner/

Joseph Zahner
Attorney for Applicants
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Regeneron Pharmaceuticals Inc.
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(914) 847-1595

UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/330,096	07/14/2014	Eric FURFINE	5050CON4	2013

26693 7590 04/02/2015
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
04/02/2015	ELECTRONIC

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patents@regeneron.com

Office Action Summary	Application No. 14/330,096	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

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- 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.
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Status

1)☒ Responsive to communication(s) filed on *14 July 2014*.

☐ 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) *1-10* 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) *1-10* is/are rejected.

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

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

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

Application Papers

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

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

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

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

Priority under 35 U.S.C. § 119

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

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

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

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

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

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

Attachment(s)

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

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

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

4) ☐ Other: _____.

DETAILED ACTION

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

Information Disclosure Statement

2. The information disclosure statements (IDS) submitted on 07 October 2014 have 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 applications should be included in the first sentence of the specification.

Claim Rejections - 35 USC § 112, 1st Paragraph (Written Description)

5. The following is a quotation of the first paragraph of 35 U.S.C. 112(a):

> (a) IN GENERAL.—The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

The following is a quotation of the first paragraph of pre-AIA 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-4, 7 and 8 are rejected under 35 U.S.C. 112(a) or 35 U.S.C. 112 (pre-AIA), first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor or a joint inventor, or for pre-AIA the inventor(s), at the time the application was filed, had possession of the claimed invention.

7. The claims are drawn quite broadly to a pre-filled syringe comprising a stable ophthalmic formulation, wherein the formulation comprises 1-100 mg/ml of a VEGF antagonist. The claims also recite wherein the VEGF antagonist is a VEGF-specific fusion protein.

8. The guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶1 "Written Description" Requirements make clear that the written description requirement for a claimed genus may be satisfied by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 3rd column).

9. In the instant case, the only factor present in the claims is a desired functional property in the form of the recitation of being a VEGF antagonist, which the specification teaches is "a compound capable of blocking or inhibiting the biological action of vascular endothelial growth factor" (see pg. 7[0046]), or a fusion protein. However, there does not appear to be an adequate written description in the specification as filed of all VEGF antagonists. While the specification provides adequate written description for a fusion protein comprising amino acids 27-457 of

SEQ ID NO:4, it does not provide adequate written description for a commensurate number of the claimed species of VEGF antagonists. The distinguishing characteristics of the claimed genus are not described. The only adequately described species is a fusion protein comprising amino acids 27-457 of SEQ ID NO:4. Accordingly, the specification does not provide adequate written description of the claimed genus.

10. *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

11. With the exception of the fusion protein referred to above, the skilled artisan cannot envision the detailed chemical structure of the encompassed antagonists, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The product itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

12. One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine

sequence.

13. Therefore, only a fusion protein comprising amino acids 27-457 of SEQ ID NO:4, but not the full breadth of the claims, meet the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Double Patenting

14. 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).

15. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the reference application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

16. The USPTO internet Web site contains terminal disclaimer forms which may be used. Please visit http://www.uspto.gov/forms/. The filing date of the application will determine what form should be used. A web-based eTerminal Disclaimer may be filled out completely online

using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to http://www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

17. Claims 1-10 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 and 17 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 1-7 and 17 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 the instant claims, 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. Therefore, the claims are overlapping in scope.

18. Claims 1-10 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 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 1-15 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 the instant claims, 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.

19. Claims 1-10 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).

20. 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. The claims in '173 patent do not recite do not recite (a) a particular concentration of the VEGFR1R2-FcΔC1(a) polypeptide, (b) wherein the fusion comprises amino acids 27-457 of SEQ ID NO:2, (c) phosphate buffer, (d) a tonicity agent such as sodium chloride or potassium chloride, (e) a stabilizing agent, (f) an organic co-solvent, or (g) having a particular pH.

21. Dix et al. (WO 2006/104852; cited by Applicant) teach stable liquid pharmaceutical formulations comprising a VEGFR1R2 fusion protein, including the VEGFR1R2-FcΔC1(a) polypeptide comprising amino acids 27-457 of SEQ ID NO:4 (See pg. 5). 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]).

22. 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.

Summary

23. 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
March 28, 2015