



**Regeneron Ex. 2022  
Fresenius v. Regeneron  
IPR2025-01269  
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| APPLICATION NO.                                                                                             | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
|-------------------------------------------------------------------------------------------------------------|-------------|----------------------|-------------------------|------------------|
| 16/739,559                                                                                                  | 01/10/2020  | Eric FURFINE         | REGN-024CON10           | 1153             |
| 96387                                                                                                       | 7590        | 03/24/2021           | EXAMINER                |                  |
| Regeneron - Bozicevic, Field & Francis<br>201 REDWOOD SHORES PARKWAY<br>SUITE 200<br>REDWOOD CITY, CA 94065 |             |                      | LOCKARD, JON MCCLELLAND |                  |
|                                                                                                             |             |                      | ART UNIT                | PAPER NUMBER     |
|                                                                                                             |             |                      | 1647                    |                  |
|                                                                                                             |             |                      | NOTIFICATION DATE       | DELIVERY MODE    |
|                                                                                                             |             |                      | 03/24/2021              | ELECTRONIC       |

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

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

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

docket@bozpat.com



***Notice of Pre-AIA or AIA Status***

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

***Status of Application, Amendments, and/or Claims***

2. The preliminary amendment filed 10 January 2020 has been received and entered in full. Claims 1-10 are pending (renumbered as claims 12-20) and the subject of this Office Action.

***Information Disclosure Statement***

3. The information disclosure statements (IDS) submitted on 10 April 2020 and 02 March 2021 have been considered by the examiner.
4. The Third Party Submission under 37 CFR 1.290 has been considered by the Examiner.

***Specification***

5. The disclosure is objected to because of the following informalities: An updated status of the parent nonprovisional applications should be included in the first sentence of the specification.

***Claim Objections***

6. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 1-9 have been renumbered 12-20.

***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-1.jsp>.

10. Claims 12-20 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 and 11-17 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 11-17 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 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). Therefore, the claims are overlapping in scope.

11. Claims 12-20 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 and 17 of U.S. Patent No. 7,608,261. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the ophthalmic formulation of the VEGF antagonist recited in the instant claims is overlapping in scope with the ophthalmic formulation of VEGF antagonist recited in claims 1-15 and 17 of U.S. Patent No. 7,608,261. Therefore, the claims are overlapping in scope.

12. Claims 12-20 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 9,340,594. 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 1-11 of U.S. Patent No. 9,340,594. Therefore, the claims are overlapping in scope.

13. Claims 12-20 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 9,914,763. 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 1-11 of U.S. Patent No. 9,914,763. Therefore, the claims are overlapping in scope.

*Summary*

14. 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 19, 2021

|                                                                                                                                                                                         |                      |                                                                                |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------------------------------------------------------------------------------|
| <b>INTERVIEW SUMMARY and<br/>AMENDMENT<br/>Under 37 CFR § 1.111</b><br><br>Address to:<br>Mail Stop Amendment<br>Commissioner for Patents<br>P.O. Box 1450<br>Alexandria, VA 22313-1450 | Attorney Docket No.  | REGN-024CON10                                                                  |
|                                                                                                                                                                                         | Confirmation No.     | 1153                                                                           |
|                                                                                                                                                                                         | First Named Inventor | Eric Furfine                                                                   |
|                                                                                                                                                                                         | Application Number   | 16/739,559                                                                     |
|                                                                                                                                                                                         | Filing Date          | January 10, 2020                                                               |
|                                                                                                                                                                                         | Group Art Unit       | 1647                                                                           |
|                                                                                                                                                                                         | Examiner Name        | Jon McClelland Lockard                                                         |
|                                                                                                                                                                                         | Title:               | <i>“VEGF Antagonist Formulations Suitable for Intravitreal Administration”</i> |

Sir:

This amendment is responsive to the Office Action dated March 24, 2021, for which a three-month period for response was given making this amendment timely filed on or before June 24, 2021.

In view of the remarks put forth below, reconsideration and allowance are respectfully requested.

**Amendments to the Specification** begin on page 2 of this paper.

**Amendments to the Claims** are reflected in the listing of claims which begins on page 3 of this paper.

**Remarks/Arguments** begin on page 10 of this paper.

## **REMARKS UNDER 37 CFR § 1.111**

### **Formal Matters**

Claims 12 and 21-83 are pending after entry of the amendments set forth herein.

Claims 1-11 were previously canceled and claims 13-20 are canceled herein without prejudice.<sup>1</sup>

New claims 21-83 are added. Support for these claims can be found throughout the originally filed application.

Claims 12 is amended to recite a “vial comprising an ophthalmic formulation suitable for intravitreal administration” Support for the amended claims can be found throughout the originally filed application, such as, for example, at ¶¶[0002], [0037], and [0048].

Claim 12 is further amended to specify that the “VEGF antagonist fusion protein is glycosylated and comprises amino acids 27-457 of SEQ ID NO:4” Support for the amended claims can be found throughout the originally filed application, such as, for example, at ¶[0046].

No new matter has been added.

### **Interview Summary**

Applicants appreciate the Examiner taking the time for a Phone Interview on May 5, 2021 with the undersigned attorney.

During the interview it was pointed out that all the pending claims are interconnected by being directed to the invention which comprises:

- (a) an ophthalmic formulation;
- (b) a VEGF antagonist active ingredient which is defined by amino acids 27-457 of SEQ ID NO 4, and
- (c) defined by the limitation “wherein at least 98% of the VEGF antagonist is present in native conformation following storage at 5°C for two months as measured by size exclusion chromatography.”

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<sup>1</sup> As noted below, claims 12 to 20 correspond to the claims 1 to 9 submitted on January 10, 2020 which were inadvertently misnumbered.

It was pointed out that the newly added claims 45 through 69 correspond to claims that were pending within the group of claims 42 – 71 that were canceled by a Supplemental Amendment filed on April 26, 2021 in the related application serial number 16/582, 486. This specific information on a related application is provided solely for the convenience of the examiner who may have examined the claims canceled and the related application serial number 16/582, 486. Complete information relating to related applications as provided below in the McKesson Statement.

No agreement was reached in the interview and the undersigned indicated a response would be filed addressing the issues raised in the Office Action dated March 24, 2021.

#### **Objections to the Specification**

The Office objects to the specification requesting inclusion of the status of the parent nonprovisional applications in the first sentence of the specification. Applicant amends the specification accordingly.

#### **Claim Objections**

The Office objects to the pending claims under 37 C.F.R. 1.126 for failing to preserve the original claim numbering through the prosecution. The Office kindly addresses this issue by renumbering misnumbered claims 1-9 (as filed on January 10, 2020) as pending claims 12-20. Applicant maintains this numbering system in the present response. Applicant therefore respectfully submits that this objection is moot.

#### **Obviousness Type Double Patenting Rejections**

Claims 12-20 were rejected under the doctrine of obviousness-type double patenting over claims 1-7 and 11-17 of issued U.S. Patent 8,092,803.

Without acquiescing to the validity of the rejection and merely to expedite prosecution of the application Applicant submits an e-Terminal Disclaimer with respect to U.S. Patent 8,092,803 thereby rendering the rejection moot.

Claims 12-20 were rejected for obviousness type-double patenting over claims 1-15 and 17 of issued U.S. Patent 7,608,261.

The rejection is respectfully traversed as applied and as it might be applied to the

presently pending claims. All the independent claims include an element relating to the stability of the protein conformation in storage over a period of time. This element is not contained within any of the claims of the '261 patent.

In view of distinguishing features between the claims as amended and the claims of the '261 patent the rejection should be reconsidered and withdrawn.

Claims 12-20 were rejected for obviousness-type double patenting over claims 1-12 of issued U.S. Patent 9,340,594.

The claims 1-12 of the '594 patent do not include elements relating to the percentage of the VEGF antagonist which maintains its conformation following storage over a given period of time. All the independent claims include an element relating to the stability of the protein conformation in storage over a period of time. In view of such the rejection should be reconsidered and withdrawn.

Claims 12-20 were rejected for obviousness-type double patenting over claims 1-12 of issued U.S. Patent 9,914,763. The rejection is traversed as applied and as it might be applied to the amended claims.

The claims of the '763 patent do not include elements relating to the stability of the VEGF antagonist over time when stored which element is included in the claims of the present application by amendment. All the independent claims include an element relating to the stability of the protein conformation in storage over a period of time. In view of such the rejection should be reconsidered and withdrawn.

#### **Statement under 37 C.F.R. §§1.56 and 1.2**

Applicants hereby advise the Examiner of the status of a co-pending application in compliance with the Applicant's duty to disclose under 37 C.F.R. §§1.56 and 1.2 ( see also MPEP §2001.06(b)) as discussed in *McKesson Info. Soln. Inc., v. Bridge Medical Inc.*, 487 F.3d 897; 82 USPQ2d 1865 (Fed. Cir. 2007).

Applicants wish to bring to the Examiner's attention U.S. Patent Application No. 11/818,463, filed June 14, 2007 which issued as U.S. Patent No. 7,608,261 on October 27, 2009.

Applicants wish to bring to the Examiner's attention U.S. Patent Application No. 12/560,885, filed September 16, 2009 which issued as U.S. Patent No. 7,807,164 on October 5, 2010.

Applicants wish to bring to the Examiner's attention U.S. Patent Application No. 12/833,417, filed July 9, 2010 which issued as U.S. Patent No. 8,092,803 on January 10, 2012.

Applicants wish to bring to the Examiner's attention U.S. Patent Application No. 13/329,770, filed December 19, 2011 which issued as U.S. Patent No. 8,481,046 on July 9, 2013.

Applicants wish to bring to the Examiner's attention U.S. Patent Application No. 13/914,996, filed June 11, 2013 which issued as U.S. Patent No. 8,802,107 on August 12, 2014.

Applicants wish to bring to the Examiner's attention U.S. Patent Application No. 14/330,096, filed July 14, 2014 which issued as U.S. Patent No. 9,340,594 on May 17, 2016.

Applicants wish to bring to the Examiner's attention U.S. Patent Application No. 15/095,606, filed April 11, 2016 which issued as U.S. Patent No. 9,914,763 on March 13, 2018.

Applicants wish to bring to the Examiner's attention U.S. Patent Application No. 15/151,776, filed May 11, 2016 which issued as U.S. Patent No. 9,580,489 on February 28, 2017.

Applicants wish to bring to the Examiner's attention U.S. Patent Application No. 15/879,294, filed January 24, 2018 which issued as U.S. Patent No. 10,400,025 on September 3, 2019.

Applicants wish to bring to the Examiner's attention U.S. Patent Application No. 16/159,269, filed October 12, 2018 which issued as U.S. Patent No. 10,464,992 on November 5, 2019.

Applicants wish to bring to the Examiner's attention U.S. Patent Application No. 16/582,486, filed September 25, 2019 for which an Office Action was mailed January 6, 2021 and a response was filed on March 2, 2021.

Applicants wish to bring to the Examiner's attention U.S. Patent Reexamination Control No. 90/014,448 of U.S. Patent No. 10,464,992, filed February 11, 2020. A Petition Under 37 C.F.R. § 1.182 to Expedite a Concurrent Petition and Petition to Vacate Reexamination Order was filed May 29, 2020 and an Opposition to Petition was filed June 12, 2020.

Applicants wish to bring to the Examiner's attention Inter Partes Review Application No. IPR2021-00402 of U.S. Patent No. 10,464,992, filed on January 7, 2021.

These documents are available on PAIR, and thus are not provided with this communication. Please inform the undersigned if there is any difficulty in obtaining the documents from PAIR.

**CONCLUSION**

Applicants submit that all the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees up to a strict limit of \$3,000.00 beyond that authorized on the credit card, but not more than \$3,000.00 in additional fees due with any communication for the above referenced patent application, including but not limited to any necessary fees for extensions of time, or credit any overpayment of any amount to Deposit Account No. 50-0815, order number REGN-024CON10.

Respectfully submitted,  
BOZICEVIC, FIELD & FRANCIS LLP

Date: 5 May 2021

By: /Karl Bozicevic, Reg. No. 28,807 /  
Karl Bozicevic, Reg. No. 28,807

Enclosure: Terminal Disclaimer to  
U.S. Patent Nos. 8,092,803

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