

**Electronically Filed**

<b>PRELIMINARY AMENDMENT Under CFR 1.115</b>  Address to: Mail Stop Patent Application Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450	Attorney Docket No.	REGN-008CIPCON
	Confirmation No.	To Be Assigned
	First Named Inventor	YANCOPOULOS, GEORGE D.
	Application Number	To Be Assigned
	Filing Date	17 December 2015
	Group Art Unit	To Be Assigned
	Examiner Name	To Be Assigned
	Title:	<i>“Use of a VEGF Antagonist to Treat Angiogenic Eye Disorders”</i>

Sir:

Prior to the examination of the above-referenced application on the merits, please enter the amendments below.

**AMENDMENTS TO THE CLAIMS**

1. (Currently Amended) A method for treating an angiogenic eye disorder in a patient, said method comprising sequentially administering to the patient a single initial dose of a VEGF antagonist, followed by one or more secondary doses of the VEGF antagonist, followed by one or more tertiary doses of the VEGF antagonist;

wherein each secondary dose is administered 2 to 4 weeks after the immediately preceding dose; and

wherein each tertiary dose is administered ~~at least 8 weeks after the immediately preceding dose on an as-needed/pro re nata (PRN) basis, based on visual and/or anatomical outcomes as assessed by a physician or other qualified medical professional;~~

**wherein the VEGF antagonist is a receptor-based chimeric molecule comprising (1) a VEGFR1 component comprising amino acids 27 to 129 of SEQ ID NO:2; (2) a VEGFR2 component comprising amino acids 130-231 of SEQ ID NO:2; and (3) a multimerization component comprising amino acids 232-457 of SEQ ID NO:2.**

2. (Original) The method of claim 1, wherein only a single secondary dose is administered to the patient, and wherein the single secondary dose is administered 4 weeks after the initial dose of the VEGF antagonist.

3. (Original) The method of claim 1, wherein only two secondary doses are administered to the patient, and wherein each secondary dose is administered 4 weeks after the immediately preceding dose.

4. (Canceled)

5. (Canceled)

6. (Original) The method of claim 1, wherein the angiogenic eye disorder is selected from the group consisting of: age related macular degeneration, diabetic retinopathy, diabetic macular edema, central retinal vein occlusion, branch retinal vein occlusion, and corneal neovascularization.

7. (Original) The method of claim 6, wherein the angiogenic eye disorder is age related macular degeneration.

8. (Currently Amended) The method of claim 1, wherein all doses of the VEGF antagonist ~~is an anti-VEGF antibody or fragment thereof, an anti-VEGF receptor antibody or fragment thereof, or a VEGF receptor-based chimeric molecule~~ are administered to the patient by topical administration or by intraocular administration.

9. - 12. (Canceled)

13 (Currently Amended) The method of claim ~~2~~ **12**, wherein all doses of the VEGF antagonist are administered to the patient by intraocular administration.

14. (Original) The method of claim 13, wherein the intraocular administration is intravitreal administration.

15. – 17. (Canceled)

18. (Currently Amended) The method of claim ~~13~~ **17**, wherein all doses of the VEGF antagonist comprise from about 0.5 mg to about 2 mg of the VEGF antagonist.

19. (Original) The method of claim 18, wherein all doses of the VEGF antagonist comprise 0.5 mg of the VEGF antagonist.

20. (Original) The method of claim 18, wherein all doses of the VEGF antagonist comprise 2 mg of the VEGF antagonist.

21. (New) The method of claim 1, wherein the VEGF antagonist is VEGFR1R2-Fc $\Delta$ C1(a) encoded by the nucleic acid sequence of SEQ ID NO:1.

**REMARKS UNDER 37 CFR § 1.115**

**Formal Matters**

Claims 1-3, 6-8, 13, 14 and 18-21 are pending after entry of the amendments set forth herein.

Claims 4, 5, 9-12 and 15-17 are canceled without prejudice.

Claims 1 and 8 are amended.

Claim 21 is added.

For the convenience of the Examiner, support for the claim amendments is made in part with reference to the allowed claims of the parent application.

The amendments to claim 1 with respect to defining the VEGF antagonists are identical to allowed claim 1 of the parent application and supported within originally pending now cancelled claim 11.

The amendments to claim 1 with respect to the tertiary dose administration are supported in the original application in paragraph [0062] Example 5, Table 2 and in paragraph [0065] Example 6.

The amendments to claim 8 are supported in originally pending now cancelled claim 12.

Formal amendments are made to claims 13 and 18 in view of the cancellation of claims 12 and 17.

Newly added claim 21 is supported in the original specification in original paragraph [0034].

No new matter has been added.

**PARENT APPLICATION**

The parent application has been allowed. Further, as indicated above, correspondence and support for the current claims relative to those of the parent application can be reviewed and confirmed. In the event the Examiner has any questions with respect to claim support or other issues in connection with the application, the Examiner is respectfully requested to contact the undersigned attorney at the indicated telephone number to arrange for an interview to expedite this position of this application.

**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).

The Applicants wish to bring to the Examiner's attention that a Notice of Allowance was mailed on October 19, 2015 in co-pending U.S. Patent Application No. 13/940,370, filed July 12, 2013.

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**CONCLUSION**

Applicant submits that all of 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-008CIPCON.

Respectfully submitted,  
BOZICEVIC, FIELD & FRANCIS LLP

Date: 17 December 2015

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