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NOTICE OF ALLOWANCE AND FEE(S) DUE

FIBROGEN, INC. 409 Illinois Street San Francisco, CA 94158 02/20/2013

EXAMINER

JEAN-LOUIS, SAMIRA JM

ART UNIT PAPER NUMBER

1627

DATE MAILED: 02/20/2013

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/928.119	12/02/2010	Volkmar Guenzler-Pukall	FP0600.4 CON	4639

TITLE OF INVENTION: STABILIZATION OF HYPOXIA INDUCIBLE FACTOR (HIF) ALPHA

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	\$885	\$300	\$0	\$1185	05/20/2013

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

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN <u>THREE MONTHS</u> FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. <u>THIS STATUTORY PERIOD CANNOT BE EXTENDED.</u> 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:

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B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

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.

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							(Depositor's name)
							(Signature)
							(Date)
APPLICATION NO.	FILING DATE		FIRST NAMED INVEN	MED INVENTOR ATTORNEY DOCKET NO.		CONFIRMATION NO.	
12/928,119	12/02/2010		Volkmar Guenzler-P	ukall		FP0600.4 CON	4639
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APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE			SUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	\$885	\$300	\$0		\$1185	05/20/2013
EXAM	INER	ART UNIT	CLASS-SUBCLAS	s			
JEAN-LOUIS,	SAMIRA JM	1627	514-307000				
"Fee Address" indi PTO/SB/47; Rev 03-0 Number is required.	ess an assignee is ident h in 37 CFR 3.11. Comp	" Indication form ed. Use of a Custom A TO BE PRINTED	or agents OR, alte (2) the name of a registered attorney 2 registered paten listed, no name with ON THE PATENT (print gnee data will appear on the NOT a substitute for filing.	single firm (having a y or agent) and the n t attorneys or agents. ill be printed.	as a memb ames of u If no nan	per a 2	ocument has been filed for
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4a. The following fee(s) are submitted: ☐ Issue Fee ☐ Publication Fee (No small entity discount permitted) ☐ Advance Order - # of Copies			The Director is h	sed. it card. Form PTO-20	038 is atta	iched.	,
a. Applicant claims	tus (from status indicated s SMALL ENTITY statu	is. See 37 CFR 1.27.				TITY status. See 37 CF	
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Authorized Signature				Date			
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12/928,119	12/02/2010	Volkmar Guenzler-Pukall	FP0600.4 CON	4639
41385 75	90 02/20/2013		EXAM	INER
FIBROGEN, INC 409 Illinois Street	2.	JEAN-LOUIS, SAMIRA JM		
San Francisco, CA	94158		ART UNIT	PAPER NUMBER
			1627	

DATE MAILED: 02/20/2013

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

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

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

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

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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.

	Application No.	Applicant(s)				
	12/928,119	GUENZLER-PUKALL ET AL.				
Notice of Allowability	Examiner	Art Unit				
	SAMIRA JEAN-LOUIS	1627				
The MAILING DATE of this communication appearable claims being allowable, PROSECUTION ON THE MERITS IS herewith (or previously mailed), a Notice of Allowance (PTOL-85) NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RI	(OR REMAINS) CLOSED in this app or other appropriate communication GHTS. This application is subject to and MPEP 1308.	olication. If not included will be mailed in due course. THIS				
1. X This communication is responsive to 11/29/12, 02/07/13, an						
 An election was made by the applicant in response to a rest requirement and election have been incorporated into this ac 		he interview on; the restriction				
3. The allowed claim(s) is/are 1-8. 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 http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PH/index.jsp or send an inquiry to <a a="" abandonment="" application.="" below.="" communication="" comply="" complying="" date"="" extendable.<="" failure="" file="" href="http://www.uspto.gov/pat</td></tr><tr><td> Acknowledgment is made of a claim for foreign priority unde a) ☐ All b) ☐ Some* c) ☐ None of the: </td><td>er 35 U.S.C. § 119(a)-(d) or (f).</td><td></td></tr><tr><td> Certified copies of the priority documents have </td><td></td><td></td></tr><tr><td>2. Certified copies of the priority documents have</td><td>• • • • • • • • • • • • • • • • • • • •</td><td></td></tr><tr><td colspan=7>3. Copies of the certified copies of the priority documents have been received in this national stage application from the</td></tr><tr><td colspan=7>International Bureau (PCT Rule 17.2(a)). * Certified copies not received:</td></tr><tr><td colspan=7>Applicant has THREE MONTHS FROM THE " in="" is="" mailing="" not="" noted="" of="" period="" reply="" requirements="" result="" td="" the="" this="" three-month="" timely="" to="" will="" with="">						
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") musi	t be submitted.					
including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date						
I dentifying 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).						
 DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL. 						
Attachment(s) 1. ☐ Notice of References Cited (PTO-892)	5. ⊠ Examiner's Amendn					
 Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 	6. ⊠ Examiner's Stateme	nt of Reasons for Allowance				
3. Examiner's Comment Regarding Requirement for Deposit	7. 🔲 Other					
of Biological Material 4. ☑ Interview Summary (PTO-413), Paper No./Mail Date <u>02/05/13</u> .						

U.S. Patent and Trademark Office PTOL-37 (Rev. 09-12)

Notice of Allowability

Part of Paper No./Mail Date 20130211

12/928.119 GUENZLER-PUKALL ET AL. Examiner-Initiated Interview Summary Examiner **Art Unit** SAMIRA JEAN-LOUIS 1627 All participants (applicant, applicant's representative, PTO personnel): (1) SAMIRA JEAN-LOUIS. (3)_____. (4)_____. (2) Christopher Turner. Date of Interview: 05 February 2013. Type: Personal [copy given to: Applicant] applicant's representative Exhibit shown or demonstration conducted: \(\simega\) Yes ΠNo. If Yes, brief description: _____. Issues Discussed □101 □102 □103 □Others (For each of the checked box(es) above, please describe below the issue and detailed description of the discussion) Claim(s) discussed: 1-3,6 and 7. Identification of prior art discussed: N/A. Substance of Interview (For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...) The examiner contacted Applicant to discuss potential allowable subject matter. Specifically, the examiner questioned applicant as to where enablement for treating tissue damage was found in the specification. While the examiner contends that applicant demonstrated stabilization of HIF alpha, nowhere in the specification did applicant demonstrae actual treatment of tissue damage as a result of hypoxia or ischemia. Additionally, the examiner contends that because applicant failed to test various compounds that stabilize HIF alpha including the elected species, applicant is also not enabled for the breadth of claim 1. Moreover, the examiner reminds applicant that because of the co-pending applications, terminal disclaimers (TD) on co-pending application 12/811,821; now U.S. Patent 8,269,008 & 8,217,043 will aslo need to be filed. Applicant stated that they will consider amending the claims and will call back. On 02/12/13, applicant called back and stated that they would consider amending the claims to treatment of hypoxic or ischemic disorders and will consider amending the compound to heterocyclic carboxamide compound that stabilized HIF-alpha since applicant has tested such compounds in the stability of HIF-alpha. The examiner agrees that applicant will be enabled for such claim and will await the filing of the TDs before claims can be issued to allowance. Applicant recordation instructions: It is not necessary for applicant to provide a separate record of the substance of interview. Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised. ☐ Attachment /SAMIRA JEAN-LOUIS/

Application No.

Applicant(s)

U.S. Patent and Trademark Office PTOL-413B (Rev. 8/11/2010)

Primary Examiner, Art Unit 1627

Paper No. 20130211 **16-01315**

DETAILED ACTION

EXAMINER'S AMENDMENT

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

Authorization for this examiner's amendment was given in a telephone interview with Christopher Turner on February 06, 2013.

The application has been amended as follows:

1. In claim 1, lines 1-3, after "for treating" <u>delete</u> "tissue damage associated with hypoxia or ischemia in a subject, the method comprising administering to the subject an effective amount of a compound that stabilizes the alpha subunit of hypoxia inducible factor (HIFα)" and <u>insert</u> "a hypoxic or ischemic-related disorder or condition in a subject, the method comprising administering to the subject an effective amount of a heterocyclic carboxamide compound that stabilizes the alpha subunit of hypoxia inducible factor (HIFα)".

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Art Unit: 1627

2. In claim 2, line 1, after "wherein the" delete "compound is a".

3. In claim 2, line 2, after "compound" delete "that".

4. In claim 3, line 1, after "wherein the" delete "tissue damage" and insert "hypoxic

or ischemic-related disorder or condition".

5. In claim 6, line 1, after "wherein the" delete "ischemia" and insert "ischemic-

related disorder or condition".

6. In claim 7, line 1, after "wherein the" <u>delete</u> "tissue damage" and <u>insert</u> "hypoxic

or ischemic-related disorder or condition".

EXAMINER'S STATEMENT OF REASONS FOR ALLOWANCE

Applicant's amendment to the claims filed November 29, 2012 has been fully

considered. In light of Applicant's amendment and the Examiner's amendment, claims

1-8 are allowed.

As for Applicant's arguments regarding the Information Disclosure Statement

(IDS), the examiner contends that such arguments are most since the IDS explicitly

recites that all citations were considered and thus a single signature requirement is all

that is needed as indicated in 37 C.F.R. 1.98.

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As for applicant's priority, the examiner is indeed in agreement that the earliest priority of this instant application is based on provisional application 60/337,082 which was filed on 12/06/01.

Applicant's argument with respect to the Obviousness Double Patenting (ODP) of claims 1 and 3-7 over co-pending application 13/128,620 has been fully considered. Given that the instant claims are now allowable and the co-pending application is laterfiled, the examiner is withdrawing such ODP rejection in order to allow the instant application to issuance.

The terminal disclaimers filed on 02/11/13 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. patent application 12/811,821, U.S. Patents 8,269,008 (formerly U.S. Patent application 12/734,895) & 8,217, 043 (formerly U.S. Patent Application 12/544,861) have been reviewed and are accepted. The terminal disclaimers have been recorded.

In light of Applicant's argument and the examiner's amendment, the 112, second paragraph rejection of claims 1-8 is hereby withdrawn.

In light of the Applicant's argument and the examiner's amendment, the 103 (a) rejection of claims 1-8 as being unpatentable over Maxwell et al. WO 02/074981 is withdrawn.

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The following is an examiner's statement of reasons for allowance: Claims 1-8 are drawn to a method for treating a hypoxic or ischemic-related disorder or condition in a subject, the method comprising administering to the subject an effective amount of a heterocyclic carboxamide compound. There is no prior art disclosing the applicant's method of treatment, particularly with the heterocyclic carboxamide compounds targeting HIFα as recited in claim 1. The closest art is Weidmann et al. (U.S. 5,658,933, cited by applicant and filed on an IDS 1449). Weidmann et al. teach heterocyclic carboxamide compounds of formula (I) for use as inhibitors of prolyl hydroxylase for inhibiting collagen synthesis and fibrotic diseases (see abstract). Additionally, Weidmann et al. teach that various fibrotic diseases can be treated including atherosclerosis (see col. 1, lines 5-9 and 24-29). However, the heterocyclic compounds of Weidmann et al. are targeted for inhibiting prolyl hydroxylases while applicant's compounds have been demonstrated to be useful in stabilizing HIF α . Since applicant's has enabled their heterocyclic compounds as useful in stabilizing HIF-α and useful in treating hypoxic and ischemic related diseases and conditions, the examiner maintains that Weidmann et al. is no longer prior art over the instant invention. Since the present claims require the heterocyclic compounds to stabilize HI-α, and Weidmann et al. alone do not render obvious claim 1, claims 1-8 are therefore allowable.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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Conclusion

Claims 1-8 are allowed.

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Samira Jean-Louis whose telephone number is 571-

270-3503. The examiner can normally be reached on 7:30-6 PM EST M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone

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.

/SAMIRA JEAN-LOUIS/

IPR2016-01315 GSK Ex. 1016, pg 476

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Primary Examiner, Art Unit 1627

02/13/2013

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