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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/093,178	04/07/2016	Spiros Liras	PC72053B	2723

28523 7590 05/16/2016
Pfizer Inc.
Attn:Legal Patent Department, Chief IP Counsel
235 East 42nd Street
New York, NY 10017

EXAMINER

AULAKH, CHARANJIT

ART UNIT	PAPER NUMBER
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1625

NOTIFICATION DATE	DELIVERY MODE
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05/16/2016

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):

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Office Action Summary	Application No. 15/093,178	Applicant(s) LIRAS ET AL.	
	Examiner Charanjit Aulakh	Art Unit 1625	AIA (First Inventor to File) Status Yes

-- 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 _____.
☐ 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) 1-13 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) 1-13 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 4/7/16
- 3) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 4) ☐ Other: _____.

DETAILED ACTION

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.
2. Claims 1-13 are pending in the application.

Claim Rejections - 35 USC § 112

3. 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.

4. 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.

5. Claims 10-13 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 enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The following eight different factors (see *Ex parte* Foreman, 230 USPQ at 547; *Wands*, In re, 858.F. 2d 731, 8 USPQ 2d 1400, Fed. Cir. 1988) must be considered in order for the specification to be enabling for what is being claimed:

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Quantity of experimentation necessary, the amount of direction or guidance provided, presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability and the breadth of claims. In the instant case, the specification is not enabling based on at least four of the above mentioned eight different factors such as quantity of experimentation necessary, the amount of direction or guidance provided, presence of working examples, state of the prior art, unpredictability and the breadth of claims.

The instant specification mentions on page 2, lines 4-5 that there still exists a need for drug delivery agents conducive to improved pharmacokinetics profiles and relates to instant compounds and their uses as ASGPR targeting agents (see page 1, lines 6-8).

Therefore, it appears that the instant compounds are simply drug delivery agents. The specification also mentions SPR binding data with the instant compounds on pages 163-165. However, first of all, there is no teaching or guidance present in the specification regarding meaning of SPR. Secondly, binding data does not tell whether the compounds are agonists or antagonists at this SPR site. There is no teaching or guidance present either in the specification or prior art showing prior art compounds having agonist/ antagonist activity at SPR site are well known to have therapeutic utility for treating every known liver disease or liver modulated disease. There are no working examples present showing efficacy of instant compounds in animal models of any liver disease or liver modulated disease condition. The instant compounds of formula (A) encompasses hundreds of thousands of compounds based on the values of variables R1 and R2 and therefore, in absence of such teachings, guidance, prior art and working

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examples, it would require undue experimentation to demonstrate efficacy of instant compounds in animal models of every known liver disease or liver modulated disease and hence their utility for treating these disease conditions.

6. The following is a quotation of 35 U.S.C. 112(b):

(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

7. The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-13 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention.

In independent claims 1 and 2, the value of variable X defined as - - - linker or a drug delivery system - - - is vague and indefinite since specific values supported by the specification are not defined.

In independent claims 1 and 2, the value of variable Y defined as - - - small molecule, an amino acid sequence, a nucleic acid sequence, an antibody, an oligomer, a polymer, genetically derived material. a liposome, a nanoparticle, dye and fluorescent probe - - - are vague and indefinite since specific values supported by the specification are not defined.

In claims 10 and 12, specific liver diseases or liver modulated diseases are not defined.

Claim 4 recites the limitation "protein and plasmid for the value of variable Y" in claim 1 or claim 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 5 recites the limitation " Cas 9 ribonucleoprotein, cas9 protein and plasmid for the value of variable Y" in claims 1 or 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 7 recites the limitation " receptor present on a hepatocyte" in claim 5. There is insufficient antecedent basis for this limitation in the claim.

Claim 9 recites the limitation " composition" in claim 7. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

(a)(1) the claimed invention was patented, described in a printed publication, or in public use, on sale or otherwise available to the public before the effective filing date of the claimed invention.

9. Claims 1, 2, 6 and 8 are rejected under 35 U.S.C. 102(a)(1) as being anticipated by Plet (Synlett, cited on applicants form 1449).

Plet discloses synthesis of precursors of Tagetotoxin. The compound 27 (see scheme 5 on page 3260) disclosed by Plet anticipates the instant claims when variable R2 represents OH and variable R1 represents –CH=CHR5 group in the instant compounds of formula (A).

Double Patenting

10. 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 double patenting rejection is appropriate where the claims at issue 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).

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).

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>.

11. Claims 1-13 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 14-28 of recently allowed application 14/714,484 (to be published as U.S. Patent No. 9,340,553). Although the claims at issue are not identical, they are not patentably distinct from each other because the compounds of the cited application/Patent anticipate the instant claims when variable R2 is other than OH group in the instant compounds of formula (A).

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charanjit Aulakh whose telephone number is (571)272-0678. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Kosar can be reached on (571)272-0913. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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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.

/Charanjit Aulakh/
Primary Examiner, Art Unit 1625

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		
	Filing Date		
	First Named Inventor	Spiros Liras	
	Art Unit		
	Examiner Name		
	Attorney Docket Number	PC72053B	

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	1	0341062	EP		1989-11-08	The Procter & Gamble Company		
	2	0341063	EP		1989-11-08	The Procter & Gamble Company		
	3	103570657	CN		2014-02-12	Tainjin Inst. of Pharmaceutical Research	Machine Translation	×

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4	103772449	CN		2014-05-07	Shanghai Sun Sail Pharmaceutical Science and Tech	Machine Translation	☒
5	103864737	CN		2014-06-18	Tainjin Inst of Pharmaceutical Research	Machine Translation	☒
6	104017031	CN		2014-09-03	Li Youxiang	Machine Translation	☒
7	104031098	CN		2014-09-10	Li Youxiang	Machine Translation	☒
8	1991/09537	WO		1991-07-11	The Procter & Gamble Company		☐
9	1993/07167	WO		1993-04-15	The Procter & Gamble Company		☐
10	2010/023594	WO		2010-03-04	Pfizer Inc.		☐
11	2011/051864	WO		2011-05-05	Pfizer Inc.		☐
12	2012/019496	WO		2012-02-16	Shanghai Hengrui Pharmaceutical Co., Ltd.	Abstract in English	☐
13	2012/041898	WO		2012-04-05	Celon Pharma Sp. Z O.O.		☐
14	2012/172566	WO		2012-12-20	Panacea Biotec Ltd.		☐

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15	2013/038429	WO		2013-03-21	Panacea Biotec Ltd.		☐
16	2014/094544	WO		2014-06-26	Tianjin Institute of Pharmaceutical Research	Abstract in English	☐
17	2014/159151	WO		2014-10-02	MSD International GMBH		☐
18	2014/161836	WO		2014-10-09	Boehringer Ingelheim Vetmedica GMBH		☐
19	2014/018671	WO		2014-01-30	Regents of the University of Minnesota		☐
20	1995/15979	WO		1995-06-15	Neorx Corporation		☐

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NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T ⁵
	1	DARBON et al., "Azido-2 Desoxy-2B-D-Galactopyrannoside Methylique, C ₇ H ₁₃ N ₃ O ₅ , et Azido-2 Desoxy-2B-D-Galactopyrannoside Ethylique, C ₈ H ₁₅ N ₃ O ₅ ", Acta Cryst. Vol. C41, pp. 1100-1104 (1985)	
	2	YAN et al., "SHR3824, a novel selective inhibitor of renal sodium glucose cotransporter 2, exhibits antidiabetic efficacy in rodent models", Acta Pharmacologica Sinica, Vol. 35, pp. 613-624 (2014)	
	3	PARK et al., "Exploration of SAR regarding glucose moiety in novel C-aryl glucoside inhibitors of SGLT2", Bioorganic & Medicinal Chemistry Letters, Vol. 21, pp. 742-746 (2011)	

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4	WITCZAK et al., "A potential CARB-pharmacophore for antineoplastic activity: Part 1", Bioorganic & Medicinal Chemistry Letters, Vol. 24, pp. 1752-1757 (2014)
5	MARTIN et al., "α-and β-Homogalactonojirimycins (α- and β-Homogalactostatins): Synthesis and Further Biological Evaluation", Bioorganic & Medicinal Chemistry, Vol. 9, pp. 1269-1278 (2001)
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16	KALGUTKAR et al., "Preclinical Species and Human Disposition of PF-04971729, a Selective Inhibitor of the Sodium-Dependent Glucose Cotransporter 2 and Clinical Candidate for the Treatment of Type 2 Diabetes Mellitus", Drug Metabolism and Disposition, Vol. 39(9), pp. 1609-1619 (2011)
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26	ARMSTRONG et al., "Total Synthesis of (+)-Zaragozic Acid C", Journal of Organic Chemistry, Vol. 65, pp. 7020-7032 (2000)
27	SUZUKI et al., "Tofogliflozin, a Potent and Highly Specific Sodium/Glucose Cotransporter 2 Inhibitor, Improves Glyemic Control in Diabetic Rats and Mice", The Journal of Pharmacology and Experimental Therapeutics, Vol. 341(3), pp. 692-701 (2012)
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37	GURJAR et al., "Zaragozic Acid A: Interesting Observations in Anhydro-ring Formation of Densely Functionalised Carbohydrate Templates", Tetrahedron Letters, Vol. 35(14), pp. 2241-2244 (1994)
38	PATERSON et al., "Studies Towards the Synthesis of the Zaragozic Acids: A Novel EEpoxide Cyclisation Approach to the Formation of the Bicyclic Acetal Core", Tetrahedron Letters, Vol. 37(48), pp. 8803-8806 (1996)
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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	
Filing Date	
First Named Inventor	Spiros Liras
Art Unit	
Examiner Name	
Attorney Docket Number	PC72053B

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Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

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A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Lisa A. Samuels/	Date (YYYY-MM-DD)	2016-04-07
Name/Print	Lisa A. Samuels	Registration Number	43080

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