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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/170,154	10/25/2018	Thierry Bouyssou	H0075.70253US00	2475
23628	7590	11/21/2019		
WOLF GREENFIELD & SACKS, P.C. 600 ATLANTIC AVENUE BOSTON, MA 02210-2206			EXAMINER COLEMAN, BRENDA LIBBY	
			ART UNIT	PAPER NUMBER
			1624	
			NOTIFICATION DATE	DELIVERY MODE
			11/21/2019	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_eOfficeAction@WolfGreenfield.com
WGS_eOfficeAction@WolfGreenfield.com

Office Action Summary

Application No.

16/170,154

Applicant(s)

Bouyssou et al.

Examiner

BRENDA L COLEMAN

Art Unit

1624

AIA (FITF) 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 23 September 2019.

☐ 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) 1-20 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) 1-19 is/are rejected.

8) ☒ Claim(s) 20 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)

3) ☐ Interview Summary (PTO-413)

Paper No(s)/Mail Date ____.

2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)

4) ☐ Other: ____.

Paper No(s)/Mail Date 2/19/2018 and 9/23/2019 times 2.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Claims 1-20 are pending in this application.

Election/Restrictions

1. The Restriction Requirement between Groups I and II dated July 23, 2019 is herein **withdrawn**.

Claim Rejections - 35 USC § 112

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.

2. Claims 18 and 19 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.

In evaluating the enablement question, several factors are to be considered. In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988); Ex parte Forman, 230 USPQ 546. The factors include: 1) The nature of the invention, 2) the state of the prior art, 3) the predictability or lack

thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the breadth of the claims, and 7) the quantity of experimentation needed.

The nature of the instant invention has claims, which embrace substituted pyridine-carbonyl-piperidine and pyridine-carbonyl-piperazine compounds.

HOW TO USE: Claims 18 and 19 are drawn to the method of treating a disease or disorder, which is associated with Transient Receptor Potential 6 ion channel activity. Any evidence presented must be commensurate in scope with the claims and must clearly demonstrate the effectiveness of the claimed compounds. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The scope of claim 18 includes diseases and/or conditions not even known at this time, which may be associated with Transient Receptor Potential 6 ion channel activity. While the treatment of depression and anxiety have been linked with Transient Receptor Potential 6 the art does not recognize use of such inhibitors as broad based drugs for treating all disorders instantly embraced. "Cancer" cannot be deemed enabled. The notion that a compound could be effective against cancer in general is contrary to our current understanding of how pharmacologicals work. All attempts to find a pharmaceutical to treat cancer generally have thus failed.

In view of the lack of direction provided in the specification regarding starting materials, the lack of working examples, and the general unpredictability of chemical reaction, it would take an undue amount of experimentation for one skilled in the art to make the claimed compounds and therefore practice the invention. To be enabling, the specification of a patent must teach those skilled in the art how to make and use the scope of the claimed invention without undue experimentation. The applicants' are not entitled to preempt the efforts of others. The test for determining compliance with 35 U.S.C. § 112, is whether the applicants have clearly defined their invention.

Evidence involving a single compound and two types of cancer was not found sufficient to establish the enablement of claims directed to a method of treating seven types of cancer with members of a class of several compounds *In re Buting* 163 USPQ 689. The remarkable advances in chemotherapy have seen the development of specific compounds to treat specific types of cancer. The great diversity of diseases falling within the “tumor” category means that it is contrary to medical understanding that any agent (let alone a genus of thousands of compounds) could be generally effective against such diseases. The intractability of these disorders is clear evidence that the skill level in this art is low relative to the difficulty of the task.

Where the utility is unusual or difficult to treat or speculative, the examiner has authority to require evidence that tests relied upon are reasonably predictive of in vivo efficacy by those skilled in the art. See *In re Ruskin*, 148 USPQ 221; *Ex parte Jovanovics*, 211 USPQ 907; MPEP 2164.05(a).

Patent Protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. Tossing out the mere germ of an idea does not constitute enabling disclosure. *Genentech Inc. v. Novo Nordisk* 42 USPQ2d 1001.

As stated in the MPEP, 2164.08 “[t]he Federal Circuit has repeatedly held that the specification must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557, 1561 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). Nevertheless, not everything necessary to practice the invention need be disclosed. In fact, what is well known is best omitted. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991). All that is necessary is that one skilled in the art be able to practice the claimed invention, given the level of knowledge and skill in the art. Further the scope of enablement must only bear a reasonable correlation to the scope of the claims. See, e.g., *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). As concerns the breadth of a claim relevant to enablement, the only relevant concern should be

whether the scope of enablement provided to one skilled in the art by the disclosure is commensurate with the scope of protection sought by the claims. In re Moore, 439 F.2d 1232, 1236, 169 USPQ 236, 239 (CCPA 1971). See also Plant Genetic Sys., N.V. v. DeKalb Genetics Corp., 315 F.3d 1335, 1339, 65 USPQ2d 1452, 1455 (Fed. Cir. 2003) (alleged pioneer status of invention irrelevant to enablement determination."

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.

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.

3. Claims 1-19 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. The following reasons apply:

- a. Claim 1 and claims dependent thereon are vague and indefinite in that it is not known what is meant by the definition of the substituents on the phenyl ring of R¹ which is not stated in the form of a proper Markush grouping.
- b. Claim 1 and claims dependent thereon are vague and indefinite in that it is not known what is meant by the definition of R² which is not stated in the form of a proper Markush grouping.
- c. Claim 1 and claims dependent thereon are vague and indefinite in that it is not known what is meant by the definition of R³ which is not stated in the form of a proper Markush grouping.
- d. Claim 2 is vague and indefinite in that it is not known what is meant by the definition of the substituents on the C₁₋₆alkyl of R¹ which is not stated in the form of a proper Markush grouping.

- e. Claim 4 is vague and indefinite in that it is not known what is meant by the moiety OCF_3 in the definition of the substituents on the phenyl ring of R^1 which is embraced by the moiety $\text{OC}_{1-6}\text{alkyl}$ optionally substituted with one to three halo.
- f. Claim 4 and claims dependent thereon are vague and indefinite in that it is not known what is meant by the definition of the heteroatoms of the ring formed when R^3 and R^4 come together to form a ring which is not stated in the form of a proper Markush grouping.
- g. Claim 4 is vague and indefinite in that it is not known what is meant by “and or a pharmaceutically acceptable salt thereof.”
- h. Claim 5 is vague and indefinite in that it is not known what is meant by R^3 is ethyl, and R^3 and R^4 join to form a spirocyclic ring.
- i. Claim 5 is vague and indefinite in that it is not known what is meant by R^3 is ethyl or methoxymethyl, and R^3 and R^5 join to form a bicyclic ring.
- j. Claim 6 is vague and indefinite in that it is not known what is meant by the definition of the R^1 together with L which is not stated in the form of a proper Markush grouping.
- k. Claim 7 is vague and indefinite in that it is not known what is meant by the definition of the R^1 together with L which is not stated in the form of a proper Markush grouping.
- l. Claim 8 is vague and indefinite in that it is not known what is meant by the definition of the R^1 together with L which is not stated in the form of a proper Markush grouping.
- m. Claim 16 is vague and indefinite in that it is not known what is meant by the open bracket in the 2nd species which does not contain a close bracket.
- n. Claim 16 is vague and indefinite in that it is not known what is meant by 1” in the 3rd species in the claim.

o. Claim 16 is vague and indefinite in that it is not known what is meant by [3,4"] in the 4th species in the claim.

p. Claim 16 is vague and indefinite in that it is not known what is meant by [3,4"] in the 3rd species on page 13 in the claim.

q. Claim 18 is vague and indefinite in that the claim provides for the use of claimed compounds, but the claim does not set forth any steps involved in determining which diseases capable of being mediated by a TRPC6 inhibitor. It is unclear which diseases are associated with each of the TRPC inhibitors. Determining whether a given disease responds or does not respond to such an inhibitor will involve undue experimentation. Suppose that a given drug, which has inhibitor properties in vitro, when administered to a patient with a certain disease, does not produce a favorable response. One cannot conclude that specific disease does not fall within this claim. Keep in mind that:

A. It may be that the next patient will respond. No pharmaceutical has 100% efficacy. What success rate is required to conclude our drug is a treatment? Thus, how many patients need to be treated? If "successful treatment" is what is intended, what criterion is to be used? If one person in 10 responds to a given drug, does that mean that the disease is treatable? One in 100? 1,000? 10,000? Will the standard vary depending on the current therapy for the disease?

B. It may be that the wrong dosage or dosage regimen was employed. Drugs with similar chemical structures can have markedly different pharmacokinetics and metabolic fates. It is quite common for pharmaceuticals to work and or be safe at one dosage, but not at another that is significantly higher or lower. Furthermore, the dosage regimen may be vital --- should the drug be given e.g. once a day, or four times in divided dosages? The optimum route of administration cannot be predicted in advance. Should our drug be given as a bolus iv or in a time release po formulation. Thus, how

many dosages and dosage regimens must be tried before one is certain that our drug is not a treatment for this specific disease?

C. It may be that our specific drug, while active in vitro, simply is not potent enough or produces such low concentrations in the blood that it is not an effective treatment of the specific disease. Perhaps a structurally related drug is potent enough or produces high enough blood concentrations to treat the disease in question, so that the first drug really does fall within the claim. Thus, how many different structurally related inhibitors must be tried before one concludes that a specific compound does not fall within the claim?

D. Conversely, if the disease responds to our second drug but not to the first, both of which are inhibitors in vitro, can one really conclude that the disease falls within the claim? It may be that the first compound result is giving the accurate answer, and that the success of second compound arises from some other unknown property, which the second drug is capable. It is common for a drug, particularly in cancer and CNS diseases, to work by many mechanisms. The history of psychopharmacology is filled with drugs, which were claimed to be a pure receptor XYZ agonist or antagonist, but upon further experimentation shown to affect a variety of biological targets. In fact, the development of a drug for a specific disease and the determination of its biological site of action usually precede linking that site of action with the disease. Thus, when mixed results are obtained, how many more drugs need be tested?

E. Suppose that our drug is an effective treatment of the disease of interest, but only when combined with some totally different drug. There are for example, agents in antiviral and anticancer chemotherapy, which are not themselves effective, but are effective treatments when the agents are combined with something else.

Consequently, determining the true scope of the claim will involve extensive and potentially inconclusive research. Without it, one skilled in the art cannot determine the actual scope of the claim. Hence, the claim is indefinite.

Double Patenting

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 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); *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 nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP §§ 706.02(I)(1) - 706.02(I)(3) for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) 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 www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

4. Claims 1-7 and 17-19 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-10 and 12-29 of copending Application No. 16/170,178 (reference application). Although the claims at issue are not identical, they are not patentably distinct from each other because the compounds, compositions and method of use of the compounds of formula (I) in 16/170,154 where Y is CH and A is N embraces the compounds, compositions and method of use of the compounds of copending Application No. 16/170,178.

This is a provisional nonstatutory double patenting rejection because the patentably indistinct claims have not in fact been patented.

Claim Objections

5. Claim 20 is 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.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRENDA L COLEMAN whose telephone number is (571)272-0665. The examiner can normally be reached on Mon-Fri 10-6 (flex).

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is

encouraged to use the USPTO Automated Interview Request (AIR) at
<http://www.uspto.gov/interviewpractice>.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0806. 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.

/BRENDA L COLEMAN/
Primary Examiner, Art Unit 1624

FORM PTO-1449/A and B (modified PTO/SB/08) INFORMATION DISCLOSURE STATEMENT BY APPLICANT				APPLICATION NO.: 16/170,154		ATTY. DOCKET NO.: H0075.70253US00	
				FILING DATE: October 25, 2018		CONFIRMATION NO.: 2475	
				FIRST NAMED INVENTOR: Thierry Bouyssou			
				GROUP ART UNIT: ~~1636~~ 1624		EXAMINER: ~~Not Yet Assigned~~ Coleman	
Sheet	1	of	2				

U.S. PATENT DOCUMENTS

Examiner's Initials #	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or Issue of Cited Document MM-DD-YYYY
		Number	Kind Code		
/B.L.C/		6,673,799	B1	Taniguchi et al.	01-06-2004
/B.L.C/		7,332,495	B2	Li et al.	02-19-2008
/B.L.C/		8,816,079	B2	Maeda et al.	08-26-2014

FOREIGN PATENT DOCUMENTS

Examiner's Initials #	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Translation (Y/N)
		Office/ Country	Number	Kind Code			
** /B.L.C/		CN	103360343	A	Kaihui Pharmaceutical Shanghai Co. Ltd.	10-23-2013	Y – Abstract Only
** /B.L.C/		CN	1381449	A	Shanghai Academy of Medical Industry	11-27-2002	Y – see US7,332,495
/B.L.C/		EP	1396487	A1	Yamanouchi Pharma Co. Ltd.	03-10-2004	
** /B.L.C/		JP	2008-239568	A	Dainippon Ink & Chemicals	10-09-2008	Y – Abstract Only
** /B.L.C/		JP	2013-107881	A	Mitsubishi Tanabe Pharma Corp.	06-06-2013	Y – Abstract Only
** /B.L.C/		WO	00/17163	A1	Yamanouchi Pharmaceutical Co., Ltd.	03-30-2000	Y – see US6,673,799
/B.L.C/		WO	02/08221	A2	Neurogen Corporation	01-31-2002	
/B.L.C/		WO	2006/044174	A2	Neurogen Corporation	04-27-2006	
/B.L.C/		WO	2007/053394	A1	Eli Lilly and Company	05-10-2007	
~~duplicate~~		~~WO~~	~~2010/080357~~	~~A1~~	~~Boehringer Ingelheim International~~	~~07-15-2010~~	
** /B.L.C/		WO	2011/136292	A1	Mitsubishi Tanabe Pharma Corp.	11-03-2011	Y – see US8,816,079
/B.L.C/		WO	2011/143365	A1	Amgen, Inc.	11-17-2011	
/B.L.C/		WO	2012/016217	A1	Rigel Pharmaceuticals, Inc.	02-02-2012	
/B.L.C/		WO	2012/158784	A2	Kamenecka et al.	11-22-2012	
/B.L.C/		WO	2013/066714	A1	Merck Sharp & Dohme Corp.	05-10-2013	
/B.L.C/		WO	2014/139144	A1	Agios Pharmaceuticals, Inc.	09-18-2014	
/B.L.C/		WO	2014/191336	A1	Hoffmann La Roche	12-04-2014	
/B.L.C/		WO	2015/048547	A2	Rigel Pharmaceuticals, Inc.	04-02-2015	
/B.L.C/		WO	2015/101957	A2	Rhizen Pharmaceuticals SA	07-09-2015	

EXAMINER: /BRENDA L COLEMAN/	DATE CONSIDERED: 11/18/2019
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

** structures and abstract only

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Sheet	2	of	2						

/B.L.C./		WO	2016/073774	A2	Flexus Biosciences, Inc.	05-12-2016	
/B.L.C./		WO	2016/138114	A1	Genentech Inc.; Constellation Pharmaceuticals Inc.	09-01-2016	
/B.L.C./		WO	2017/222930	A1	Rutgers, The State University of New Jersey	12-28-2017	
/B.L.C./		WO	2018/170225	A1	Athenex, Inc.	09-20-2018	

OTHER ART -- NON PATENT LITERATURE DOCUMENTS

Examiner's 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, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
/B.L.C./		International Search Report and Written Opinion mailed January 21, 2019 for Application No. PCT/EP2018/079276.	

[NOTE – No copies of U.S. patents, published U.S. patent applications, or pending, unpublished patent applications stored in the USPTO's Image File Wrapper (IFW) system, are included. See 37 CFR § 1.98 and 1287OG163. Copies of all other patent(s), publication(s), unpublished, pending U.S. patent applications, or other information listed are provided as required by 37 CFR § 1.98 unless 1) such copies were provided in an IDS in an earlier application that complies with 37 CFR § 1.98, and 2) the earlier application is relied upon for an earlier filing date under 35 U.S.C. § 120.]

EXAMINER: /BRENDA L COLEMAN/	DATE CONSIDERED: 11/18/2019
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

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		Number	Kind Code		
/B.L.C./		2004/0016224	A1	Haaken et al.	01-29-2004
/B.L.C./		2007/0021472	A1	Zhu et al.	01-25-2007
/B.L.C./		2010/0234603	A1	Linghu et al.	09-16-2010
/B.L.C./		2011/0257196	A1	Lu et al.	10-20-2011

FOREIGN PATENT DOCUMENTS

	Examiner's Initials #	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Translation (Y/N)
			Office/Country	Number	Kind Code			
**	/B.L.C./		CN	107176927	A	Jinler Pharmaceuticals Co. Ltd.	09-19-2017	Y – Abstract Only
**	/B.L.C./		CN	107540636	A	Chengdu Beisikairui Biotechnology Co. Ltd.	01-05-2018	Y – Abstract Only
**	/B.L.C./		JP	2007/254391	A	Japan Science & Technology Agency	10-04-2007	Y – Abstract Only
	/B.L.C./		WO	03/090752	A1	Pfizer Products Inc.	11-06-2003	
	/B.L.C./		WO	91/09594	A1	Virginia Commonwealth University	07-11-1991	
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	/B.L.C./		WO	2008/110611	A1	Novartis AG	09-18-2008	
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**	/B.L.C./		WO	2018/159827	A1	Univ. Kyoto	09-07-2018	Y – Abstract Only

OTHER ART – NON PATENT LITERATURE DOCUMENTS

EXAMINER: /BRENDA L. COLEMAN/	DATE CONSIDERED: 11/18/2019
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** structures and abstract only

FORM PTO-1449/A and B (modified PTO/SB/08) INFORMATION DISCLOSURE STATEMENT BY APPLICANT				APPLICATION NO.: 16/170,154		ATTY. DOCKET NO.: H0075.70253US00	
				FILING DATE: October 25, 2018		CONFIRMATION NO.: 2475	
				FIRST NAMED INVENTOR: Thierry Bouyssou			
				GROUP ART UNIT: ~~1625~~ 1624		EXAMINER: ~~Patricia L. Morris~~ Coleman	
Sheet	2	of	4				

Examiner's 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, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
/B.L.C./		ALESSANDRI-HABER et al., TRPC1 and TRPC6 channels cooperate with TRPV4 to mediate mechanical hyperalgesia and nociceptor sensitization. J Neurosci. 2009 May 13;29(19):6217-28. doi: 10.1523/JNEUROSCI.0893-09.2009.	
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				FILING DATE: October 25, 2018		CONFIRMATION NO.: 2475	
				FIRST NAMED INVENTOR: Thierry Bouyssou			
				GROUP ART UNIT: ~~1623~~ 1624		EXAMINER: ~~Patricia L. Morris~~ Coleman	
Sheet	3	of	4				

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				FILING DATE: October 25, 2018		CONFIRMATION NO.: 2475	
				FIRST NAMED INVENTOR: Thierry Bouyssou			
				GROUP ART UNIT: ~~T625~~ 1624		EXAMINER: ~~Patricia L. Morris~~ Coleman	
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[NOTE – No copies of U.S. patents, published U.S. patent applications, or pending, unpublished patent applications stored in the USPTO's Image File Wrapper (IFW) system, are included. See 37 CFR § 1.98 and 1287OG163. Copies of all other patent(s), publication(s), unpublished, pending U.S. patent applications, or other information listed are provided as required by 37 CFR § 1.98 unless 1) such copies were provided in an IDS in an earlier application that complies with 37 CFR § 1.98, and 2) the earlier application is relied upon for an earlier filing date under 35 U.S.C. § 120.]

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor: Thierry Bouyssou
Application No.: 16/170,154
Confirmation No.: 2475
Filed: October 25, 2018
For: INHIBITORS OF TRPC6
Examiner: Patricia L. Morris
Art Unit: 1625

Certificate of Electronic Filing under 37 C.F.R. § 1.8

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being transmitted via the Office's electronic filing system in accordance with 37 C.F.R. § 1.6(a)(4).

Dated: September 23, 2019

Electronic Signature for Cara B. Dawson: /Cara B. Dawson/

MAIL STOP AMENDMENT

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

**STATEMENT FILED PURSUANT TO THE DUTY OF
DISCLOSURE UNDER 37 C.F.R. §§ 1.56, 1.97 AND 1.98**

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§ 1.56, 1.97 and 1.98, the undersigned requests consideration of this Information Disclosure Statement.

PART I: Compliance with 37 C.F.R. § 1.97

This Information Disclosure Statement has been filed before the mailing of a first Office Action on the merits in the above-identified case.

No fee or certification is required.

PART II: Information Cited

The undersigned hereby makes of record in the above-identified application the information listed on the attached form PTO-1449 (modified PTO/SB/08). The order of presentation of the references should not be construed as an indication of the importance of the references.

The undersigned hereby makes the following additional information of record in the above-identified application.

The undersigned would like to bring to the Examiner's attention the following co-pending applications that may contain subject matter related to this application:

<u>Serial No.</u>	<u>Filing Date</u>	<u>Inventor(s)</u>	<u>Docket No.</u>
/B.L.C/ *16/170,178	October 25, 2018	Bouyssou et al.	H0075.70254US00

*A copy of this reference is not provided as the Office has waived the requirement under 37 C.F.R. § 1.98(a)(2)(iii) for submitting a copy of a cited U.S. patent application if it is scanned to the Image File Wrapper system and is available on Private PAIR .

/BRENDA L COLEMAN/ 11/18/2019

PART III: Remarks

Documents cited anywhere in the Information Disclosure Statement are enclosed unless otherwise indicated. It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 (modified PTO/SB/08) be signed by the Examiner to evidence that the cited information has been fully considered by the United States Patent and Trademark Office during the examination of this application;
3. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, the undersigned makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.

By submitting this Information Disclosure Statement, the undersigned makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

By submitting this Information Disclosure Statement, the undersigned makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. § 102.

Notwithstanding any statements by the undersigned, the Examiner is urged to form his or her own conclusion regarding the relevance of the cited information.

An early and favorable action is hereby requested.

The Director is hereby authorized to charge any deficiency or credit any overpayment in the fees occasioned by the filing of this Information Disclosure Statement to our Deposit Account No. 23/2825 under Docket No. H0075.70253US00 from which the undersigned is authorized to draw.

Respectfully submitted,

Electronic signature: /Jeffrey D. Hsi/
Jeffrey D. Hsi, PhD
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Docket No.: H0075.70253US00
Date: September 23, 2019