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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/471,919	08/28/2014	Mitsutaka Nakamura	472340US40CONT	1054
22850	7590	10/19/2016	EXAMINER	
OBLON, MCCLELLAND, MAIER & NEUSTADT, L.L.P. 1940 DUKE STREET ALEXANDRIA, VA 22314			MAEWALL, SNIGDHA	
			ART UNIT	PAPER NUMBER
			1612	
			NOTIFICATION DATE	DELIVERY MODE
			10/19/2016	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. 14/471,919	Applicant(s) NAKAMURA ET AL.	
	Examiner SNIGDHA MAEWALL	Art Unit 1612	AIA (First Inventor to File) Status No

-- 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 4/8/16.
 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) 20-28 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) 20-28 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 _____.
- 3) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 4) Other: _____.

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

Detailed Action

Restriction/Election

Applicant's arguments regarding prosecuting all the claims is considered. Claims 20-28 are pending and are included in the prosecution.

Claim Rejections - 35 USC § 103

The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 20-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al. (US 6,964,962); as evidenced by Pozuelo et al. (US PG pub. 2001/0047010 A1).

Wong et al. teach 0.05 to 7500 mg/day/patient of SM-13496 (Instant compound) can be used to treat schizophrenia (see column 4, lines 51-58; column 7, lines 37-38 and Table in column 8, line 16), which details the daily dose of SM-13496 (instant compound) that can be given to the patient and thus may be a once a day administration. Moreover, Wong et al. teaches 0.05 to 7500 mg/day/patient of SM-13496 can be used to treat schizophrenia (column 4, lines 51-58; and Table in column 8, line 16). The amount disclosed overlaps with the claimed amount and thus creates case of obviousness. The prior art does not disclose the exact claimed values, but does

overlap: in such instances even a slight overlap in range establishes a prima facie case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003). The reference discloses that the common side effects associated with treatment of schizophrenia is weight gain and sleepiness, however the object of the invention is to provide an effective treatment of schizophrenia with reduced side effects that are known, see column 4, lines 25-27 and column 5, lines 4-5., column 10, lines 13-15. The reference teaches diseases that are treated are schizophrenia and bipolar disorder, see column 9, lines 55-56).

The prior art discloses compositions containing SM-13496 in column 7, lines 37-38 along with other antipsychotic agents such as aripiprazole, ziprasidone, sertindole etc and treatment of schizophrenia, bipolar disorder and several other diseases and disorders as disclosed in column 9, lines 35-65. The prior art is not anticipatory insofar as the antipsychotic agent, SM-13496 as claimed and the disease to be treated must be selected from various lists/locations in the reference in an amount that overlaps with the claimed amount. It would have been obvious, however, to utilize SM-13496 from among various agents taught by the reference for treating schizophrenia or bipolar disorder since each agent is taught as being useful in treating schizophrenia or bipolar disorder in prior art.

Since this modification of the prior art represents nothing more than “the predictable use of prior art elements according to their established functions” a *prima facie* case of obviousness exists. See KSR v. Teleflex, 82 USPQ2d 1385, 1396 (2007). See also Ex parte Perrier, Appeal 2012-003888 (PTAB (2014)) (USSN 11/174,414)

(applying the KSR standard of obviousness to selection of xanthan polymer and chloride of sebacic acid as polymer and crosslinker for forming prior art polymer networks since “this combination is merely a predictable used of prior art elements according to their established functions” – see fifth page of the decision). Wong et al. does not explicitly teach treating manic depressive psychosis. Pozuelo et al. teaches that manic depressive psychosis is typically referred to as bipolar illness, see [0005]. Therefore based on the teachings of Pozuelo et al. it would appear reasonable to conclude that treatment of bipolar illness by using the instantly claimed compound as taught by Wong et al. would include treatment of manic depressive psychosis as claimed because Pozuelo et al. teaches that manic depressive psychosis is typically referred to as bipolar illness, see [0005].

Nonstatutory double patenting rejection

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.

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