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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,021	02/18/2005	Mitsutaka Nakamura	0020-5041PUS2	3141

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EXAMINER	
MAEWALL, SNIGDHA	
ART UNIT	PAPER NUMBER
1612	

NOTIFICATION DATE	DELIVERY MODE
06/12/2009	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.

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Office Action Summary	Application No.	Applicant(s)	
	10/525,021	NAKAMURA ET AL.	
	Examiner	Art Unit	
	Snigdha Maewall	1612	

-- 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 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, 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 *16 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ 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

4)☒ Claim(s) *1,2,5,8,11 and 20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-2, 5, 8, 11 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ 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).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

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).

a)☐ All b)☐ Some * c)☐ None of:

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) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

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DETAILED ACTION

Status of the Claims

1. Receipt of Applicants arguments/Remarks and **RCE** filed on 03/16/09 are acknowledged.

Claims 3-4, 6-7, 9-10, 12-19 and 21have been canceled.

Claim 1 has been amended.

Accordingly, claims **1-2, 5, 8, 11 and 20** are being examined on the merits herein.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –
(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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3. Claims 1-2, 5, 8, 11 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 464846 by Saji et al.

Saji teaches a method of treatment of schizophrenia (see page 3, lines 1-4 and page 15). Saji et al. teaches oral preparations of the claimed compound, see page 33. The reference teaches dosage for adult daily dose to be from about 1 mg to 1000 mg, preferably from about 5 to 100 mg and in case of oral dosage to be from about 0.1 mg to 100 mg, preferably from about 0.3 mg to 50 mg, (see page 13, lines 25-30). The reference teaches in Table 4, the amount of compound 101, an antipsychotic, which is same as the instant claimed compound to be 10.3 mg/kg and similar antipsychotic compound to be 26.5 mg/kg on page 15.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 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 of this title, 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 negatived by the manner in which the invention was made.

5. Claims 1-2, 5, 8, 11 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 464846 by Saji et al.

Saji et al. teaches oral preparations of the claimed compound, see page 33. The reference teaches dosage for adult daily dose to be from about 1 mg to 1000 mg, preferably from about 5 to 100 mg and in case of oral dosage to be from about 0.1 mg to 100 mg, preferably from about 0.3 mg to 50 mg, (see page 13, lines 25-30). The reference teaches in Table 4, the amount of compound 101, an antipsychotic, which is

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same as the instant claimed compound to be 10.3 mg/kg and similar antipsychotic compound to be 26.5 mg/kg on page 15.

Although the reference does not teach exactly the same range 5 mg to 120 mg, however, the reference also teaches that the dosage of the imide compound or its pharmaceutically acceptable salt varies greatly with the symptom, age and weight of the patient, the dosage form and the administration mode, see page 13, lines 25-30.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to optimize the amount of drug and arrive at the optimum dosage level by doing experimental manipulations with minimum side effects. It is to be noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 223, 235 (CCPA 1955) absent evidence to the contrary

6. Claims 1-2, 5, 8, 11 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sommerville et al. (WO 03/066039 A1) in view of Wong et al. (US 6,964,962) by itself or in view of EP 464846 by Saji et al.

It is noted that (1R,2S,3R,4S)-N-[(1R,2R)-2-[4-(1,2-benzoisothiazol-3-yl)-1-piperazinyl-methyl]-1-cyclohexylmethyl]-2,3-bicyclo[2.2.1] heptanedicarboximide hydrochloride is known in the art as SM-13496 (see page 7, lines 5-8 of the specification). Thus, SM-13496 is the hydrochloride salt of (1R,2S,3R,4S)-N-[(1R,2R)-

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