PATENT
Attorney Docket No. 05273.0127-01000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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

Prior Application Art Unit: 1612 Prior Application Examiner: Snigdha MAEWELL

Commissioner: This is a request for filing a

☒ Continuation ☐ Continuation-in-Part ☐ Divisional Application under 37 C.F.R. § 1.53(b) of pending prior Application No. 10/525,021, filed February 18, 2005 of Mitsutaka Nakamura et al. AGENT FOR TREATMENT OF SCHIZOPHRENIA

1. ☐ Enclosed is a complete copy of the prior application as originally filed. I hereby verify that the attached papers are a true copy of prior Application No. 10/525,021 as filed on February 18, 2005, which is incorporated herein by reference.

2. ☐ Enclosed is an AIA Transition Application Statement under 1.55(j), 1.78(a)(6), and/or 1.78(c)(6).

3. ☐ Enclosed is a Request for Non-Publication of Application and Certification Under 35 U.S.C. § 122(b)(2)(B)(i).

4. ☒ A Preliminary Amendment is enclosed.

5. ☒ The filing fee is calculated on the basis of the claims existing in the prior application as amended in the Preliminary Amendment filed herewith.

6. ☐ A new oath or declaration is enclosed.

7. ☒ An Application Data Sheet is enclosed.

Basic Utility Application Filing Fee					$280	$ 280.00
Search Fee					$600	600.00
Examination Fee					$720	720.00
	Number of Claims		Basic	Extra		
Total Claims	7	-	20	0	x $ 80	0.00
Independent Claims	1	-	3	0	x $420	0.00
☐ Presentation of Multiple Dep. Claim(s)					+ $780	
Size Fee: Paper Filing Total Application Pages (specification, drawings, printed sequence or computer listing, preliminary amendment)	[Total] - 100 ÷ 50 = [number]* x $400 *Rounded up to next whole number					0
Additional Fee for Paper Filing New Application $400 (DELETE if filing new application via EFS Web - fee not required for EFS new application submissions)						0
Size Fee: EFS-Web Filing Total Application Pages (specification, drawings, printed sequence or computer listing, preliminary amendment)	23 X .75 - 100 ÷ 50 = 0* x $400 *Rounded up to next whole number					0
[Surcharge under § 1.16(f) $140 for postponing filing of oath or declaration]						140.00
Subtotal						$ 1,740.00
Reduction by 1/2 if small entity **[for e-filing ONLY: small entity fee for Basic filing fee - $70)**						-
TOTAL FEES DUE						$ 1,740.00

8. ☒ Authorization to charge a credit card for the fee of $1,740.00 is submitted herewith.

9. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required including fees due under 37 C.F.R. § 1.16 and any other fees due under 37 C.F.R. § 1.17, or credit any overpayment during the pendency of this application to Deposit Account No. 06-0916.

10. ☐ New acceptable drawings are enclosed.

11. ☒ The prior application is assigned of record to: DAINIPPON SUMITOMO PHARMA CO., LTD.

12. ☐ Small entity status is appropriate and applies to this application.

13. ☒ The power of attorney in the prior application is to FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P., Customer No. 22,852.

14. ☐ A **Listing Under 37 C.F.R. § 1.32(c)(3) of Ten or Fewer Practitioners to be Recognized by the PTO as Being of Record** is attached.

15. ☐ The power appears in the original declaration of the prior application.

16. ☐ Since the power does not appear in the original declaration, a copy of the power in the prior application is enclosed.

17. ☒ Please address all correspondence to FINNEGAN, HENDERSON, FARABOW, GARRETT and DUNNER, L.L.P., **Customer Number 22,852**.

18. ☐ A new power of attorney is enclosed.

19. ☐ Also enclosed is

PETITION FOR EXTENSION. If any extension of time is necessary for the filing of this application, including any extension in parent Application No. 10/525,021, filed February 18, 2005, for the purpose of maintaining copendency between the parent application and this application, and such extension has not otherwise been requested, such an extension is hereby requested, and the Commissioner is authorized to charge necessary fees for such an extension to Deposit Account 06-0916.

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: August 28, 2014

By: Kimberly D. Braslow
Kimberly D. Braslow
Reg. No. 63,219
(202) 408-4000

DESCRIPTION

AGENT FOR TREATMENT OF SCHIZOPHRENIA

TECHNICAL FIELD

The present invention relates to a novel method for treatment of schizophrenia and a novel therapeutic agent used therein. More particularly, the present invention relates to a method for improving schizophrenia without being accompanied by extrapyramidal symptoms by orally administering a prescribed dose of a specific bicycloheptane-dicarboximide derivative once a day, and a therapeutic agent used in said method.

BACKGROUND ART

Schizophrenia (split personality) is a kind of endogenous psychosis, and it is developed mainly during adolescence, and after a chronic course, the personality of patient is progressively decayed, and some of patients may culminate in a mental decay. The symptoms of this disease are, for example, positive symptoms often observed during the early stage of the disease such as hallucination, delusion, etc., or negative symptoms such as apathy and withdrawal, or cognitive dysfunction such as impairments of concentration and learning abilities, etc. Moreover, there are other symptoms such as depression, anxiety, etc. as related symptoms thereof.

Medication is mainly employed in the treatment of schizophrenia, but the treatment of schizophrenia should be continued for a long time, and even though schizophrenia is once healed, there is a large risk of reoccurring of schizophrenia after drug withdrawal so that it is necessary to continue the medication forever. Therefore, any side effects of medication may always be serious problems, and based on

this perspective, it has been desired to develop a medicine being suitable for prolonged medication.

The agents for treatment of schizophrenia are various medicaments such as ones classified in the category of antipsychotic, for example, phenothiazine derivatives (e.g., chlorpromazine, methoxypromazine, etc.), thioxanthin derivatives having a similar structure to phenothiazine (e.g., chlorprothixene, flupentixol, etc.), benzamide derivatives (e.g., sulpiride, sultopride, etc.), thienodiazepine derivatives (e.g., clotiazepam, etizolam, etc.), and further butyrophenone derivatives (e.g., haloperidol, triperidol, etc.), diphenylbutylamine derivatives (e.g., pimozide, etc.), etc.

However, phenothiazine derivatives, phenothiazine analogues, and butyrophenone derivatives may cause serious side effects of extrapyramidal symptoms showing parkinsonism such as the stiff gait of skeletal muscles, tremor of muscles, lack of facial expression, salivation, etc. Further, diphenylbutylamine derivatives may cause extrapyramidal symptoms in addition to insomnia. In addition, these conventional antipsychotics may be effective on only some of symptoms among positive symptoms, negative symptoms, cognitive dysfunctions of schizophrenia, and there has been no drug being effective on all of these symptoms.

Therefore, it has been desired to develop a safe medicament which exhibits an excellent effect on various schizophrenia as an antipsychotic without causing side effects such as extrapyramidal symptoms.

On the other hand, it has been known that the imide derivative of the following formula, which was found by the co-workers of the present inventors, may be useful as an antipsychotic (c.f., neuroleptic agent, antiaxiety, etc.), especially as an agent for treatment of schizophrenia, senile insanity, manic depressive psychoses, and

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