

Docket No.: 0020-5041PUS2  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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In re Patent Application of:  
Mitsutaka NAKAMURA et al.

Application No.: 10/525,021

Confirmation No.: 3141

Filed: February 18, 2007

Art Unit: 1612

For: AGENT FOR TREATMENT OF  
SCHIZOPHRENIA

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Examiner: KRASS, F. F.

**AMENDMENT IN RESPONSE TO NON-FINAL OFFICE ACTION**

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

Sir:

In response to the Office Action issued on December 17, 2007, the period for response having been extended by three (3) month, the following amendments and remarks are respectfully submitted in connection with the above-identified application:

**Amendments to the specification** begin on **page 2** of this paper;

**Amendments to the claims** begin on **page 3** of this paper;

**Remarks** begin on **page 6** of this paper; and

**Copies of the following are attached to this paper:**

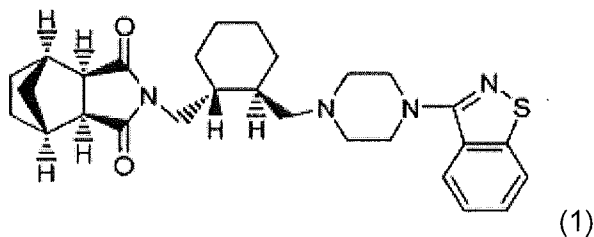
- Erhart et al. (2006),
- Laughren and Levin (2005),
- Alphs (2006)
- Kane (2005), and
- Kirkpatric et al. (2005)

**AMENDMENTS TO THE SPECIFICATION****Please amend the Abstract as follows:**

The present invention provides a novel method for treatment of schizophrenia which can improve wide-ranging symptoms of schizophrenia, especially positive symptoms and negative symptoms without being accompanied by extrapyramidal symptoms, which comprises orally administering as an active compound (1R,2S,3R,4S)-N-[(1R,2R)-2-[4-(1,2-benzisothiazol-3-yl)-1-piperazinylmethyl]-1-cyclohexylmethyl]-2,3-bicyclo[2.2.1]heptanedicarboxyimide or a pharmaceutically acceptable salt thereof (e.g., hydrochloride) at a daily dose of 5 mg to 120 mg once a day to a patient with schizophrenia, and a therapeutic agent to be used in ~~said~~ the method.

### AMENDMENTS TO THE CLAIMS

1. **(Currently Amended)** A method for ~~treatment of~~ treating schizophrenia in a patient suffering from schizophrenia, without said treatment being accompanied by any extrapyramidal symptoms, which comprises orally administering a once daily dose of 5 mg to 120 mg of the active compound: (1R,2S,3R,4S)-N-[(1R,2R)-2-[4-(1,2-benzothiazol-3-yl)-1-piperazinylmethyl]-1-cyclohexylmethyl]-2,3-bicyclo[2.2.1]heptanedicarboxyimide of the formula (1):



or a pharmaceutically acceptable salt thereof to a patient suffering from schizophrenia ~~once a day,~~ wherein the administration of said active compound improves the positive symptoms of schizophrenia and/or the negative symptoms of schizophrenia and/or the cognitive dysfunction of schizophrenia.

2. **(Currently Amended)** The method for ~~treatment according to~~ of claim 1, wherein the pharmaceutically acceptable salt of said active compound is (1R,2S,3R,4S)-N-[(1R,2R)-2-[4-(1,2-benzothiazol-3-yl)-1-piperazinylmethyl]-1-cyclohexylmethyl]-2,3-bicyclo[2.2.1]heptanedicarboxyimide hydrochloride.

3. – 4. **(Canceled)**

5. **(Currently Amended)** The method for ~~treatment according to~~ of claim 1 or claim 2, which ~~comprises orally administering~~ wherein 20 mg to 80 mg of said ~~the~~ active compound is administered to said patient.

~~:(1R,2S,3R,4S)-N-[(1R,2R)-2-[4-(1,2-benzothiazol-3-yl)-1-piperazinylmethyl]-1-cyclohexylmethyl]-2,3-bicyclo[2.2.1]heptanedicarboxyimide hydrochloride at a daily dose of 20 mg to 80 mg once a day.~~

6. – 7. **(Canceled)**

8. **(Currently Amended)** ~~The method for treatment of schizophrenia in the chronic stage according to~~ claim 1 or claim 2, wherein said patient is in a chronic stage of schizophrenia, and wherein 20 mg to 80 mg of said active compound is administered to said patient.

~~which improves schizophrenia without being accompanied by any extrapyramidal symptoms by orally administering the active compound: (1R,2S,3R,4S)-N-[(1R,2R)-2-[4-(1,2-benzothiazol-3-yl)-1-piperazinylmethyl]-1-cyclohexylmethyl]-2,3-bicyclo[2.2.1]heptanedicarboxyimide hydrochloride at a daily dose of 5 mg to 80 mg once a day.~~

9. – 10. **(Canceled)**

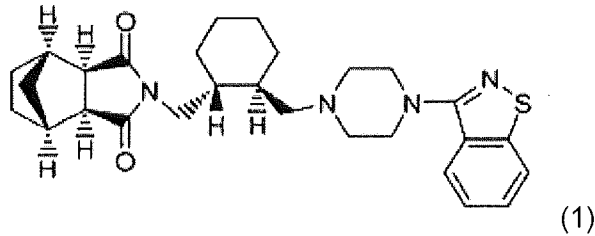
11. **(Currently Amended)** ~~The method for treatment according to~~ claim 8, which comprises orally administering wherein 50 mg to 80 mg of said the active compound is administered to said patient.

~~:(1R,2S,3R,4S)-N-[(1R,2R)-2[4-(1,2-benzothiazol-3-yl)-1-piperazinylmethyl]-1-cyclohexylmethyl]2,3-bicyclo[2.2.1]heptanedicarboximide hydrochloride at a daily dose of 10 mg to 40 mg once a day.~~

12. – 19. **(Canceled)**

20. **(New)** A method for treating the positive symptoms and the negative symptoms of schizophrenia in a patient suffering from schizophrenia which comprises orally administering to said patient a preparation comprising a single active compound or a pharmaceutically acceptable salt of said active compound, wherein 5 mg to 120 mg of said active compound is administered

once a day to said patient, and wherein said active compound is (1R,2S,3R,4S)-N-[(1R,2R)-2-[4-(1,2-benzothiazol-3-yl)-1-piperazinylmethyl]-1-cyclohexylmethyl]-2,3-bicyclo[2.2.1]heptanedicarboximide of the formula (1):



21. (New) The method of claim 1 wherein the administration of said active compound improves the negative symptoms of schizophrenia and/or the cognitive dysfunction of schizophrenia.

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