

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

---

In re Patent Application of:  
Mitsutaka NAKAMURA et al.

Application No.: 10/525,021

Confirmation No.: 3141

Filed: February 18, 2005

Art Unit: 1612

For: AGENT FOR TREATMENT OF  
SCHIZOPHRENIA

---

Examiner: S. Maewall

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

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

Sir:

**INTRODUCTORY COMMENTS**

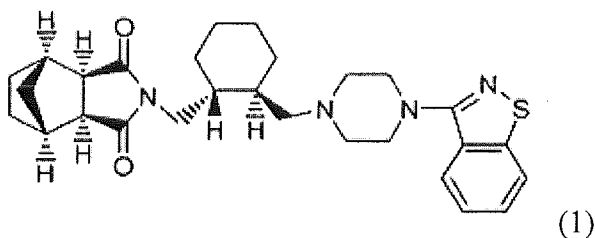
In response to the Office Action issued on June 12, 2009, the period for response being extended by petition filed herewith, the following amendments and remarks are respectfully submitted in connection with the above-identified application:

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

**Remarks/Argument** begin on page 4 of this paper.

**AMENDMENTS TO THE CLAIMS**

1. **(Currently Amended)** A method for treating the negative symptoms of schizophrenia and/or the cognitive dysfunction of 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-benzisothiazol-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, ~~wherein the administration of said active compound improves the negative symptoms of schizophrenia and/or the cognitive dysfunction of schizophrenia.~~

2. **(Currently amended)** The method of claim 1, 22 or 23 wherein the pharmaceutically acceptable salt of said active compound is (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 hydrochloride.

3. – 4. **(Canceled)**

5. **(Currently amended)** The method of ~~claim 1 or claim 2~~ any one of claims 1, 2, 22 and 23, wherein 20 mg to 80 mg of said active compound is administered to said patient.

6. – 7. **(Canceled)**

8. **(Currently amended)** The method of ~~claim 1 or claim 2~~ any one of claims 1, 2, 22 and 23, 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.

9. – 10. **(Canceled)**

11. **(Previously Presented)** The method of claim 8, wherein 50 mg to 80 mg of said active compound is administered to said patient.

12. – 19. **(Canceled)**

20. **(Canceled)**

21. **(Cancelled)**

22. **(New)** The method of claim 1, which is a method for treating the negative symptoms of schizophrenia in a patient.

23. **(New)** The method of claim 1, which is a method for treating the cognitive dysfunction of schizophrenia in a patient.

## REMARKS

### *Status of the Claims*

Claim 20 is canceled. Claim 1 is amended to clarify the class of symptoms being treated; further amendments to claim 1 are editorial in nature. Dependency is amended in claims 2, 5 and 8 to include new claims 22 and 23, which respectively recite each of the individual alternative symptom classes recited in claim 1.

No new matter has been added.

### *Anticipation by Saji*

Claims 1, 2, 5, 8, 11 and 20 are rejected under 35 USC § 102(b) as anticipated by Saji et al. EP '846. This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

The Examiner asserts that Saji EP '846 teaches treatment of schizophrenia by administration of the claimed compound with a daily dose, for an adult, of from 1 to 1000 mg, or from 0.1 to 100 mg if administered orally.

Saji EP '846 does **not** anticipate the present invention. The present claim 1 recites treatment of two particular classes of symptoms of the particular disease (schizophrenia) by administration of a particular compound (Lurasidone or its salts).

On the other hand, as explained in previous responses, Saji EP '846 describes the compound very broadly (see, formula I at p. 4) and names specifically at least 200 compounds that are to be used for "antipsychotic" treatments broadly stated (p. 3, lines 3-4). Nowhere in Saji EP '846 is the particular compound recited in the present claim 1 (Lurasidone) associated with effective treatment of schizophrenia particularly, and especially there is no association of Lurasidone with the treatment of negative symptoms of schizophrenia or with the treatment of cognitive dysfunction arising from schizophrenia.

Furthermore, there is no indication in Saji EP '846 that Lurasidone is effective in treating these symptoms without inducing any extrapyramidal symptoms. There is not any recognition by Saji EP '846 that "negative symptoms" are something that should be addressed in an effective treatment of schizophrenia nor that extrapyramidal symptoms are to be avoided.

It is well-established that a broad, generic teaching is not anticipatory of a claim directed to a particular combination of elements in the absence of direction within the reference toward that combination. See, *In re Petering* 133 USPQ 275 (CCPA 1962). Saji EP '846 does not provide any such direction as explained above, and so does not anticipate the present invention.

Anticipation also requires that each and every feature of the claim be described in the reference. As explained above, Saji EP '846 fails to disclose at least one feature in the present claim 1, and so fails to anticipate claim 1 or the claims dependent therefrom. The instant rejection must be withdrawn for this second reason as well.

### ***Obviousness***

Claims 1, 2, 5, 8, 11 and 20 are rejected under 35 USC § 103(a) as obvious over Saji EP '846. Claims 1, 2, 5, 8, 11 and 20 are also rejected under 35 USC § 103(a) as obvious over Sommerville WO '039 in view of Wong '962 alone or in view of Saji EP '846. These rejections are respectfully traversed. Reconsideration and withdrawal thereof are requested.

The Examiner asserts that the references teach the treatment of schizophrenia by the claimed compound with the claimed dosage, particularly...

"Sommerville et al. further teaches positive and negative symptoms are often increased during the acute phase, or the florid psychotic phase, of schizophrenia ..." (the Office Action, page 5, second paragraph), and

"There is nothing in Saji's reference which describes that negative symptoms were still prevailing while treating schizophrenia with the claimed compound." (the Office Action, page 7, third paragraph).

It is true that it has been known that negative symptoms are included in the symptoms of schizophrenia. However, it has been considered before filing of the present application that the known drugs for treatment of schizophrenia are effective for the treatment of positive symptoms of schizophrenia but not sufficiently effective for the treatment of negative symptoms of schizophrenia. At the time the present application was filed, there was no drug sufficiently effective for the treatment of negative symptoms of schizophrenia. This long-felt need in the art

# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

## LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

## FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

## E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.