

DOCKET NO: 472340US

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF :
MITSUTAKA NAKAMURA, ET AL. : EXAMINER: MAEWALL, SNIGDHA
SERIAL NO: 14/471,919 :
FILED: AUGUST 28, 2014 : GROUP ART UNIT: 1612
FOR: AGENT FOR TREATMENT OF :
SCHIZOPHRENIA

AMENDMENT

COMMISSIONER FOR PATENTS
ALEXANDRIA, VIRGINIA 22313

Commissioner:

In response to the Office Action dated October 19, 2016, please amend the above-identified application as follows:

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks/Arguments begin on page 14 of this paper.

IN THE CLAIMS

Please amend the claims as follows:

Claims 1-19 (Canceled).

Claim 20 (Currently Amended): A method for treating schizophrenia in a patient without a clinically significant weight gain, or manic depressive psychoses in a patient, without causing clinically significant body weight gain in the patient, the method comprising:
administering orally to the patient a 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]heptanedicarboximide or a pharmaceutically acceptable salt thereof at a dose of from 20 to 120 mg/day such that the patient does not experience a clinically significant weight gain.

Claim 21 (Currently Amended): The method of claim 20, wherein ~~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]heptanedicarboximide hydrochloride is administered.

Claim 22 (Canceled).

Claim 23 (Currently Amended): The method of claim ~~[[20]]~~ 21, wherein ~~said active compound is administered to said patient orally~~ the administering is conducted such that the patient does not experience a clinically significant weight gain after six weeks of administration.

Claim 24 (Currently Amended): The method of claim ~~[[20]] 23~~, wherein ~~said active compound is administered to said patient~~ the administering is conducted without concurrently administering another antipsychotic medication.

Claim 25 (Currently Amended): The method of claim ~~[[20]] 21~~, wherein ~~said active compound is administered to said patient for a period of at least six weeks~~ further comprising:

detecting a weight gain after six weeks of administration.

Claim 26 (Currently Amended): The method of claim 20, wherein said patient has a BPRS score of at least 42 and wherein the patient's BPRS score is significantly reduced from a baseline measurement prior to the administering ~~of said active compound~~.

Claim 27 (Currently Amended): The method of claim ~~[[20]] 23~~, wherein ~~said active compound is administered~~ the dose is from 40 to 120 mg once daily.

Claim 28 (Currently Amended): ~~The method of claim 20, wherein~~ [[the]] A method [[is]] for treating manic depressive psychoses psychosis in a patient without a clinically significant weight gain, comprising:

administering orally to the patient (1R,2S,3R,4S)-N-[(1R,2R)-2-[4-(1,2-benzisothiazol-3-yl)-1-piperazinylmethyl]-1-cyclohexylmethyl]-2,3-bicyclo[2.2.1]heptanedicarboximide or a pharmaceutically acceptable salt thereof at a dose of from 20 to 120 mg/day such that the patient does not experience a clinically significant weight gain.

Claim 29 (New): The method of claim 28, wherein (1R,2S,3R,4S)-N-[(1R,2R)-2-[4-(1,2-benzisothiazol-3-yl)-1-piperazinylmethyl]-1-cyclohexylmethyl]-2,3-bicyclo[2.2.1]heptanedicarboximide hydrochloride is administered.

Claim 30 (New): The method of claim 29, wherein the administering is conducted such that the patient does not experience a clinically significant weight gain after six weeks of administration.

Claim 31 (New): The method of claim 29, further comprising:
detecting a weight gain after six weeks of administration.

Claim 32 (New): The method of claim 30, wherein the administering is conducted without concurrently administering another antipsychotic medication.

Claim 33 (New): The method of claim 30, wherein the dose is 20 mg once daily.

Claim 34 (New): The method of claim 30, wherein the dose is 40 mg once daily.

Claim 35 (New): The method of claim 30, wherein the dose is 60 mg once daily.

Claim 36 (New): The method of claim 30, wherein the dose is 80 mg once daily.

Claim 37 (New): The method of claim 30, wherein the dose is 120 mg once daily.

Claim 38 (New): The method of claim 29, wherein the dose is 20 mg, 40 mg, 60 mg, 80 mg or 120 mg once daily.

Claim 39 (New): The method of claim 23, wherein the dose is 20 mg once daily.

Claim 40 (New): The method of claim 23, wherein the dose is 40 mg once daily.

Claim 41 (New): The method of claim 23, wherein the dose is 60 mg once daily.

Claim 42 (New): The method of claim 23, wherein the dose is 80 mg once daily.

Claim 43 (New): The method of claim 23, wherein the dose is 120 mg once daily.

Claim 44 (New): The method of claim 21, wherein the dose is 20 mg, 40 mg, 60 mg, 80 mg or 120 mg once daily.

Claim 45 (New): A method of treating a patient with an antipsychotic without a clinically significant weight gain in the patient, comprising:

orally administering the antipsychotic to the patient once daily at a dose of from 20 to 120 mg such that the patient does not experience a clinically significant weight gain,

wherein the antipsychotic 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]heptanedicarboximide or a pharmaceutically acceptable salt thereof.

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