## Attorney Docket No. PRD2901USNP

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### In The United States Patent And Trademark Office

**Applicants**: An Vermeulen et al. **Art Unit**: 1627

Serial No.: 12/337,144 Examiner: Claytor, D. Renee

Filed: 12/17/2008 Confirmation Number: 3172

For: DOSING REGIMEN ASSOCIATED WITH LONG ACTING INJECTABLE

PALIPERIDONE ESTERS

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

## **AMENDMENT**

Sir:

This paper is in response to the Notice of Allowance dated March 13, 2015.

Entry of the following amendment is respectfully requested.

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

Remarks/Arguments begin on page 8 of this paper.



## **Amendments to the Claims:**

This listing of claims replaces all prior versions, and listings, of claims in the captioned application.

## **Listing of Claims**:

- 1. (Currently Amended) A dosing regimen for administering paliperidone palmitate to a psychiatric patient in need of treatment for schizophrenia, schizoaffective disorder, or schizophreniform disorder comprising
  - (1) administering intramuscularly in the deltoid of a patient in need of treatment a first loading dose of about 150 mg-eq. of paliperidone as paliperidone palmitate formulated in a sustained release formulation on the first day of treatment;
  - (2) administering intramuscularly in the deltoid muscle of the patient in need of treatment a second loading dose of about 100 mg-eq. of paliperidone as paliperidone palmitate formulated in a sustained release formulation on the 6<sup>th</sup> to about 10th day of treatment; and
  - (3) administering intramuscularly in the deltoid or gluteal muscle of the patient in need of treatment a <u>first</u> maintenance dose of about 25 mg-eq. to about 150 mg-eq. of paliperidone as paliperidone palmitate in a sustained release formulation <u>a month (±7 days) after the second loading dose.</u> on about the 34th to about the 38th day of treatment.
- 2. (Currently Amended) The dosing regimen of claim 1 wherein after administration of the first maintenance dose of a sustained release depot formulation of paliperidone palmitate is administered, subsequent maintenance doses of from about 25 mg-eq. to 150 mg-eq. are administered in the deltoid or gluteal muscle of the psychiatric patient in need of treatment at monthly (±7 days) intervals after the 30<sup>th</sup>-day of treatment.



- 3. (Previously Presented) The dosing regimen of claim 1 wherein the sustained release formulation is an aqueous nanoparticle suspension.
- 4. (Currently Amended) A dosing regimen for administering paliperidone palmitate to a psychiatric patient in need of treatment for psychotic disorder comprising
- (a) administering intramuscularly in the deltoid of a patient in need of treatment a first loading dose of about 150 mg-eq. of paliperidone as paliperidone palmitate formulated in a sustained release formulation on the first day of treatment;
- (b) administering intramuscularly in the deltoid muscle of the patient in need of treatment a second loading dose of about 100 mg-eq. of paliperidone as paliperidone palmitate formulated in a sustained release formulation on the eighth day of treatment; and
- (c) administering intramuscularly in the deltoid or gluteal muscle of the patient in need of treatment a <u>first</u> maintenance dose of about 25 mg-eq. to about 150 mg-eq. of paliperidone as paliperidone palmitate in a sustained release formulation <u>a</u> month (±7 days) after the second loading dose. on about the 36th day of treatment.
- 5. (Previously Presented) The dosing regimen of claim 4 wherein the sustained release formulation is an aqueous nanoparticle suspension of.
- 6. (Cancelled)
- 7. (Cancelled)
- 8. (Cancelled)
- 9. (Cancelled)
- 10. (Cancelled)



- 11. (Cancelled)
- 12. (Cancelled)
- 13. (Previously Presented) The dosing regimen of claim 4 wherein the psychiatric patient is in need of treatment for psychotic disorder wherein the psychotic disorder is schizophrenia.
- 14. (Canceled)
- 15. (Previously Presented) The dosing regimen of claim 4 wherein the psychiatric patient is in need of treatment for a psychotic disorder wherein the psychotic disorder is schizoaffective disorder.
- 16. (Currently Amended) A dosing regimen for administering paliperidone palmitate to a renally impaired psychiatric patient in need of treatment for schizophrenia, schizoaffective disorder, or schizophreniform disorder comprising
  - (a) administering intramuscularly in the deltoid of a renally impaired psychiatric patient in need of treatment a first loading dose of from about 75 mg-eq. of paliperidone as paliperidone palmitate formulated in a sustained release formulation on the first day of treatment;
  - (b) administering intramuscularly in the deltoid muscle of the patient in need of treatment a second loading dose of from about 75 mg-eq. of paliperidone as paliperidone palmitate formulated in a sustained release formulation on the 6<sup>th</sup> to about 10th day of treatment; and
  - (c) administering intramuscularly in the deltoid or gluteal muscle of the patient in need of treatment a <u>first</u> maintenance dose of about 25 mg-eq. to about 75 mg-eq. of paliperidone as paliperidone palmitate in a sustained release



formulation <u>a month (±7 days) after the second loading dose.</u> on about the 34th to about the 38th day of treatment.

- 17. (Currently Amended) The dosing regimen of claim 16 wherein <u>after</u> the <u>first</u> maintenance dose of a sustained release formulation of paliperidone palmitate is administered monthly, subsequent maintenance doses of from about 25 mg-eq. to 150 mg-eq. are administered in the deltoid or gluteal muscle of the psychiatric patient in need of treatment at monthly (±7) intervals after the 30<sup>th</sup> day of treatment.
- 18. (Previously Presented) The dosing regimen of claim 16 wherein the sustained release formulation is an aqueous nanoparticle suspension.
- 19. (Currently Amended) A dosing regimen for administering paliperidone palmitate to a renally impaired psychiatric patient in need of treatment for psychotic disorder comprising
- (a) administering intramuscularly in the deltoid of a renally impaired psychiatric patient in need of treatment a first loading dose of from about 75 mg-eq. of paliperidone as paliperidone palmitate formulated in a sustained release formulation on the first day of treatment;
- (b) administering intramuscularly in the deltoid muscle of the patient in need of treatment a second loading dose of from about 75 mg-eq. of paliperidone as paliperidone palmitate formulated in a sustained release formulation on the eighth day of treatment; and
- (c) administering intramuscularly in the deltoid or gluteal muscle of the patient in need of treatment a <u>first</u> maintenance dose of about 25 mg-eq. to about 50 mg-eq. of paliperidone as paliperidone palmitate in a sustained release formulation <u>a month</u> (±7 days) after the second loading dose. on about the 36th day of treatment.
- 20. (Previously Presented) The dosing regimen of claim 19 wherein the sustained release formulation is an aqueous nanoparticle suspension.



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