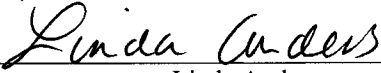


**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re the Application of:	
Inventors: Gregory T. Went	Group Art Unit: 1627
Serial No.: 13/536,525	Examiner: Carter, Kendra D.
Filed: June 28, 2012	Confirmation No.: 1096
Title: <b><i>Method for Administering an NMDA Receptor Antagonist to a Subject</i></b>	Customer No.: 94584
	<b><u>Certificate of Electronic Filing</u></b>
	I hereby certify that this Preliminary Amendment and all marked attachments are being deposited by Electronic Filing on September 6, 2012 by using the EFS-Web patent filing system and addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.
	By:  Linda Anders

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

**PRELIMINARY AMENDMENT**

Dear Madam:

Applicants respectfully request entry of the proposed amendments prior to examination and allowance of the pending claims.

An **Amendment to the Specification** begins on page **2** of this paper.

A **Complete Listing of Claims** begins on page **3** of this paper.

**Remarks** begin on page **6** of this paper.

**AMENDMENT TO THE SPECIFICATION**

After Paragraph [00101], please insert the following paragraph and table:

--Compositions described herein provide a dC/dT of 2.1 ng/mL/hr or less, as shown, e.g., in the following table, which summarizes the pharmacokinetic properties of memantine in exemplary IR and SR formulations:

Active Agents Formulation Type	Memantine IR Administration		Memantine SR Formulation	
Quantity/dose (mg)	10		28	
Dosing Freq (hr)	12		24	
Tmax	3		24	
T1/2	60		60	
Vd (L)	600		600	
dC/dT 4hr	4.0	ng/ml	2.1	ng/ml
Cmax/Cmean2-16	1.6		1.7	
Cmax2-16	30.7		29.3	
Cmean2-16	18.8		17.4	
Ratio Data	<u>2-24 hr</u>		<u>2-24 hr</u>	
min	7.75		3.47	
max	27.99		8.06	
Average	14.64		5.24	
SD	4.99		1.34	
Cratio.var (%)	34%		26%	

**AMENDMENTS TO THE CLAIMS**

This listing of claims will replace all prior versions and listings in the above-referenced patent application. The foregoing amendments are without prejudice and do not constitute an admission regarding the patentability of the amended subject matter and should not so be construed.

**Listing of Claims**

1. (Currently Amended) A method of treating a patient with a neurological disorder selected from the group consisting of Alzheimer's disease, dementia, Parkinson's disease, and neuropathic pain, comprising:

administering to said subject once daily a sustained release oral dosage form comprising 22.5 mg to 30 mg of memantine or a pharmaceutically acceptable salt thereof and a component that sustains release of said memantine or salt thereof,

wherein said sustained release memantine provides a change in mean plasma concentration of memantine as a function of time ( $dC/dT$ ) that is: (a) less than about 50% of the  $dC/dT$  provided by the same quantity of an immediate release form of memantine, determined in a time period between 0- $T_{max}$  of the immediate release form of memantine; and (b) 2.1 ng/ml/hr or less, determined in a time period of 0 to 4 hours; wherein  $dC/dT$  is measured in a single-dose human PK study.

2. (Original) The method of claim 1, wherein the  $dC/dT$  of 2.1 ng/mL/hr or less is determined in a time period of 2 to 4 hours.

3. (Canceled).

4. (Canceled).

5. The method of claim 1, wherein the sustained release oral dosage form comprises 25 mg to 30 mg memantine or a pharmaceutically acceptable salt thereof.

6. The method of claim 5, wherein the  $dC/dT$  of 2.1 ng/mL/hr or less is determined in a time period of 2 to 4 hours.

7. (Canceled).

8. (Canceled).

9. (Original) The method of claim 1, wherein the sustained release oral dosage form comprises 28 mg memantine or a pharmaceutically acceptable salt thereof.

10. (Original) The method of claim 9, wherein the  $dC/dT$  of 2.1 ng/mL/hr or less is determined in a time period of 2 to 4 hours.

11. (Canceled).

12. (Canceled).

13. (Currently Amended) A method of treating a patient with a neurological disorder selected from the group consisting of Alzheimer's disease, dementia, Parkinson's disease, and neuropathic pain, comprising:

administering to said subject once daily a sustained release oral dosage form comprising 22.5 mg to 30 mg of memantine or a pharmaceutically acceptable salt thereof and a component that sustains release of said memantine or salt thereof,

wherein said sustained release memantine provides a change in mean plasma concentration of memantine as a function of time ( $dC/dT$ ) that is: (a) less than about 50% of the  $dC/dT$  provided by the same quantity of an immediate release form of memantine, determined in a time period between 0 hours and 6 hours of administration of memantine; and (b) 2.1 ng/ml/hr or less, determined in a time period of 0 to 4 hours; wherein  $dC/dT$  is measured in a single-dose human PK study.

14. (Original) The method of claim 13, wherein the  $dC/dT$  of 2.1 ng/mL/hr or less is determined in a time period of 2 to 4 hours.

15. (Canceled).

16. (Canceled).
17. (Original) The method of claim 13, wherein the sustained release oral dosage form comprises 25 mg to 30 mg memantine or a pharmaceutically acceptable salt thereof.
18. (Original) The method of claim 17, wherein the  $dC/dT$  of 2.1 ng/mL/hr or less is determined in a time period of 2 to 4 hours.
19. (Canceled).
20. (Canceled).
21. (Original) The method of claim 13, wherein the sustained release oral dosage form comprises 28 mg memantine or a pharmaceutically acceptable salt thereof.
22. (Original) The method of claim 21, wherein the  $dC/dT$  of 2.1 ng/mL/hr or less is determined in a time period of 2 to 4 hours.
23. (Canceled).
24. (Canceled).
25. (Canceled).
26. (Canceled).
27. (Canceled).
28. (Canceled).
29. (Canceled).
30. (Canceled).

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