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: ***Method for Administering an NMDA Receptor Antagonist to a Subject***	Customer No.: 94584
	Certificate of Electronic Filing 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 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	2-24 hr		2-24 hr	
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-Tmax 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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