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Table with 5 columns: APPLICATION NO., FILING DATE, FIRST NAMED INVENTOR, ATTORNEY DOCKET NO., CONFIRMATION NO. Includes application details for Gregory T. Went and examiner information for Kendra D. Carter.

Please find below and/or attached an Office communication concerning this application or proceeding.
The time period for reply, if any, is set in the attached communication.



<b>Office Action Summary</b>	<b>Application No.</b> 11/399,879	<b>Applicant(s)</b> WENT ET AL.	
	<b>Examiner</b> KENDRA D. CARTER	<b>Art Unit</b> 1627	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1)  Responsive to communication(s) filed on 05 November 2010.
- 2a)  This action is **FINAL**.                      2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4)  Claim(s) 12,23,24,28,29,50,51,53,55-60,62,66,67,69-72 and 74-85 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) 12,23,24,28,29,50,51,53,55-60,62,66,67,69-72 and 74-85 is/are rejected.
- 7)  Claim(s) \_\_\_\_\_ is/are objected to.
- 8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a)  All    b)  Some \*    c)  None of:
1.  Certified copies of the priority documents have been received.
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/01/10;11/5/10</u> . | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Claims 12, 23, 24, 28, 29, 50, 51, 53, 55-60, 62, 66, 67, 69-72 and 74-85 are pending. Claims 23, 24, 50, 51, 71 and 72 are amended, and claims 74-85 are new. Claims 1-11, 13-22, 25-27, 30-49, 52, 54, 61, 63-65, 68 and 73 are cancelled. All pending claims are drawn to the elected species memantine (species of NMDAR antagonist), donepezil (species of AChEi), and dementia of the Alzheimer's type (species of condition) in the reply filed on February 18, 2010.

In light of further consideration and applicant's arguments being persuasive to overcome the 35 U.S.C. 102(e) rejection, the NEW NON-FINAL rejections are below. Particularly, Moebius does not specifically teach memantine in an extended release formulation especially compared to the arguments over the properties of the extended release formulation. The previously made 35 U.S.C. 102(e) and 103(a) rejection are withdrawn. The Double Patenting rejections are upheld because the claims were not found allowable and a terminal disclaimer has not been provided.

The Went Declaration is discussed below. Applicant's arguments with respect to the 35 U.S.C. 102(e) and 103(a) rejection have been considered but are moot in view of the new ground(s) of rejection.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

**1) Claims 12, 23-25, 28, 29 and 50 are provisionally rejected on the ground of nonstatutory double patenting over claims 12-14 and 21-29 of copending Application No. 12/753,769. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.**

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: an extended formulation of memantine and donepezil with the same dissolution profile that can be administered simultaneously in a single composition. The amounts of memantine can range between 10 to 80, 20 to 60, or 40 to 80 mg per dose.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other

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