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Table with 5 columns: APPLICATION NO., FILING DATE, FIRST NAMED INVENTOR, ATTORNEY DOCKET NO., CONFIRMATION NO. Includes details for application 14/729,660 filed 06/03/2015 by William H. McKenna, attorney docket no. 241957.000596, confirmation no. 2426. Also includes examiner AKHOON, KAUSER M, art unit 1642, and notification date 04/08/2016 via electronic mode.

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.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 14/729,660	<b>Applicant(s)</b> MCKENNA ET AL.	
	<b>Examiner</b> KAUSER AKHOON	<b>Art Unit</b> 1642	<b>AIA (First Inventor to File) Status</b> No

-- 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 MONTHS 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 12/11/2015 and 02/16/2016.  
 A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on \_\_\_\_\_.
- 2a)  This action is **FINAL**.                      2b)  This action is non-final.
- 3)  An election was made by the applicant in response to a restriction requirement set forth during the interview on \_\_\_\_\_; the restriction requirement and election have been incorporated into this action.
- 4)  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\***

- 5)  Claim(s) 170-199 is/are pending in the application.  
5a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 6)  Claim(s) \_\_\_\_\_ is/are allowed.
- 7)  Claim(s) 170-199 is/are rejected.
- 8)  Claim(s) \_\_\_\_\_ is/are objected to.
- 9)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

\* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see [http://www.uspto.gov/patents/init\\_events/pph/index.jsp](http://www.uspto.gov/patents/init_events/pph/index.jsp) or send an inquiry to [PPHfeedback@uspto.gov](mailto:PPHfeedback@uspto.gov).

**Application Papers**

- 10)  The specification is objected to by the Examiner.
- 11)  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).

**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).

**Certified copies:**

- a)  All    b)  Some\*\*    c)  None of the:
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)  Notice of References Cited (PTO-892)
- 2)  Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)  
Paper No(s)/Mail Date 11/24/2015, 12/11/2015 and 03/03/2016.
- 3)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 4)  Other: \_\_\_\_\_

The present application is being examined under the pre-AIA first to invent provisions.

### **DETAILED ACTION**

Claims 170-199 are currently pending and under examination.

#### ***Withdrawn rejections***

Applicants' amendment and arguments filed 12/11/2015 and 02/16/2016 are acknowledged and have been fully considered. The Examiner has re-weighed all the evidence of record. Any rejection and/or objection not specifically addressed below is herein withdrawn.

Claim 172-173 was objected to for minor informalities. Claims 172-175, 180-186, 190-195, 197 and 199 are rejected under 35 U.S.C. 112, second paragraph. Applicants' arguments were persuasive and the rejection has been withdrawn.

Claims 170-175 and 187-199 were rejected under pre-AIA 35 U.S.C. § 102(b) as being anticipated by Bartholomaeus *et al.* ("Bartholomaeus", US Patent Publication No 2005/0031546). Applicants' amendment to claims have overcome this rejection.

#### ***Information Disclosure Statement***

Applicant's Informational Disclosure Statements, filed on 11/24/2015, 12/11/2015 and 03/03/2016 have been considered. The signed and initialed PTO 1449s have been mailed with this action.

#### ***Affidavit under – 37 CFR § 1.132***

The Affidavit under 37 CFR 1.132 filed 12/11/2015 is insufficient to overcome the rejection of claims 170-199 based upon Bartholomaeus or Bartholomaeus in view of Wright as set forth in the last Office action because: Applicant have amended claims to recite that high

Art Unit: 1642

molecular weight polyethylene oxide is at least 79% by weight of the total weight of said uncoated tablet for 10/15/20/30 mg oxycodone and at least 65% by weight of the total weight of said uncoated tablet for 40/60/80 mg oxycodone would be present in the composition.

However, the data presented is not commensurate in scope to that instantly claimed. The tablets for which the data is presented both have PEO of 80% or 96% and no data was presented for 65-79% and did not compare the claimed subject matter with the closest prior art, i.e. Bartholomaeus *et al.* (“Bartholomaeus”, US Patent Publication No 2005/0031546). See MPEP 716.02(e).

As such the Affidavit does not have supportive data which would differentiate the compositions as taught by Bartholomaeus in view of Wright with that instantly claimed.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

Art Unit: 1642

3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under pre-AIA 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of pre-AIA 35 U.S.C. 103(c) and potential pre-AIA 35 U.S.C. 102(e), (f) or (g) prior art under pre-AIA 35 U.S.C. 103(a).

**Claims 170-199 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Bartholomaeus *et al.* (“Bartholomaeus”, US Patent Publication No 2005/0031546) in view of Wright *et al.* (“Wright”, US Patent Publication No 2003/0068375).**

Applicants' instant claims are directed to a method of treating pain by administering a pharmaceutical tablet comprising an opioid or pharmaceutically acceptable salt thereof with a high molecular weight polyethylene oxide with a MW from 4,000,000 or 7,000,000, said high molecular weight polyethylene oxide is at least 79% by weight of the total weight of said uncoated tablet for 10/15/ 20/30 mg oxycodone and at least 65% by weight of the total weight of said uncoated tablet for 40/60/80 mg oxycodone, these tablets being prepared by compression shaped and air cured with temperature at least 62 °C for a duration of at least 5 minutes. Further, *optional* inclusion of additional components are interpreted as compositions that do not contain that component.

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