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Table with 5 columns: APPLICATION NO., FILING DATE, FIRST NAMED INVENTOR, ATTORNEY DOCKET NO., CONFIRMATION NO. Includes details for application 14/729,634 filed 06/03/2015 by William H. McKenna.

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EXAMINER
AKHOON, KAUSER M

ART UNIT 1642
PAPER NUMBER

NOTIFICATION DATE 05/24/2016
DELIVERY MODE ELECTRONIC

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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Office Action Summary	Application No. 14/729,634	Applicant(s) MCKENNA ET AL.	
	Examiner KAUSER AKHOON	Art Unit 1642	AIA (First Inventor to File) Status 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 11/23/2015 and 02/16/2015.
 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 or send an inquiry to 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 11/23/2015, 01/04/2016 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.

Withdrawn rejections

Applicants' amendment and arguments filed 11/23/2015 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.

Claims 172-174, 190-196 and 199 were rejected under 35 U.S.C. 112, second paragraph. Applicants' arguments were persuasive and the rejection has been withdrawn.

Claims 187, 188 and 189 were rejected under 35 U.S.C. 112(d) or 35 U.S.C. 112 (pre-AIA), 4th paragraph. Applicants' arguments were persuasive and the rejection has been withdrawn.

Information Disclosure Statement

Applicant's Informational Disclosure Statements, filed on 11/23/2015, 01/04/2016 and 03/03/2016 have been considered. The signed and initialed PTO 1449s have been mailed with this action.

Declaration under – 37 CFR § 1.132

The Affidavit under 37 CFR 1.132 filed 11/23/2015 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 molecular weight polyethylene oxide is at least 79% by weight of the total weight of said

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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 § 102

The following is a quotation of the appropriate paragraphs of pre-AIA 35 U.S.C. § 102

(b) that forms the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 170-174 and 187-199 stand 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’ claims are directed to a pharmaceutical table comprising oxycodone 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 with a MW from 4,000,000 or 7,000,000, said high molecular weight polyethylene oxide is at least 65% or

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79% by weight of the total weight of said uncoated tablet alone or in combination with the low molecular weight polyethylene oxide, 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.

Bartholomaus teaches a tablet comprising 20 mg (13.3% by wt of the tablet) oxycodone hydrochloride and 110 mg (73.3% by wt of the tablet) polyethylene oxide of molecular weight 7,000,000 (page 11, paragraph [0136]). Bartholomaus teaches preparing his tablets by tableting (shaping) and heating at 80 °C under pressure for at least 15 seconds (page 10, paragraph [0117]). Thereby reading upon claims 170-170.

Bartholomaus teaches his tablets are prepared accordingly to the procedure described in his Example 1, which teaches that the tablets were prepared by heating the mixture (80 °C) under pressure for at least 15 seconds of opioid with the polyethylene oxide, therefore reading upon instant claims 172-174. Further, it should be noted that claims 172-174 are product-by-process claims. Please note that in product-by-process claims, “once a product appearing to be substantially identical is found and a 35 U.S.C. 102/103 rejection [is] made, the burden shifts to the applicant to show an unobvious difference.” MPEP 2113. This rejection under 35 U.S.C. 102/103 is proper because the “patentability of a product does not depend on its method of production.” *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985). As a practical matter, the Patent Office is not equipped to manufacture products by the myriad number of processes put before it and then obtain prior art products and make physical comparisons therewith.” *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972). Please note that the Patent and

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