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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/553,107	09/03/2009	Brian Ault	POZN.P0026US	5949

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EXAMINER	
JUSTICE, GINA CHIEUN YU	

ART UNIT	PAPER NUMBER
1617	

NOTIFICATION DATE	DELIVERY MODE
03/26/2015	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. 12/553,107	Applicant(s) AULT ET AL.	
	Examiner GINA YU JUSTICE	Art Unit 1617	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 *December 16, 2014*.

☐ 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) *19,29,33,34,40,42 and 45* 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) *19,29,33,34,40,42 and 45* 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 _____.

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

Applicant's response filed on December 16, 2014 has been received. No claim amendment has been made; Claims 19, 29, 33, 34, 40, 42 and 45 remain pending.

In this Office action, all claim rejections as indicated in the previous Office action dated June 16, 2014 are maintained for reasons of record.

Maintained: Claim Rejections - 35 USC § 103

The following is a quotation of 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 negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 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 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 19, 29, 33, 34, 40, 42 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hassan-Alin et al. ("Lack of drug-drug interaction between esomeprazole and naproxen in healthy subjects", Gastroenterology, 124(4), Supp. 1, p. A541, April 2003) ("Hassan-Alin" hereunder) in view of Plachetka (US 6926907 B2).

Hassan-Alin that no drug-drug interactions between esomeprazole and naproxen was observed in a study conducted with 32 healthy subjects and mean weight of 69 Kg who received once/day dose of 40 mg of esomeprazole and twice/day 250 mg of naproxen or the two drugs in combination for 7 days. Blood samples for determination of the drugs were collected 24 hours post-dose on day 7 and were analyzed using normal-phase liquid chromatography with UV-detection. Pharmacokinetic parameters o[the two drugs were estimated by non-compartmental analysis and were calculated using analysis of variance (ANOVA). The study teaches that naproxen was chosen as a widely used representative of non-selective NSAIDs. The reference also teaches that ***esomeprazole provides more time with intragastric pH>4 than other proton pump inhibitors and is expected to be even more effective than these for the prevention of NSAID-associated ulcers and provide GI protection***. The study concludes that there was no evidence of any increase of adverse events as esomeprazole was well tolerated both alone and in combination in naproxen. The study further suggests that naproxen can be administered without dosage alteration, which is interpreted to mean that the amount of the NSAID which potentially damages GI track does not need to be reduced.

The user group of the Hassan-Alin study were healthy individuals and not in need of NSAID therapy as presently claimed. The regime in the study is also different from the claimed method in that the presently claimed method requires AM and PM dosage of 500 mg naproxen, which is greater than the amount used in prior art (250 mg twice a day). However, administering to patients having inflammatory diseases an amount of a NSAID greater than what was given to healthy subjects would have been obvious to those skilled in pharmaceutical art.

For example, Plachetka teaches a method for a coordinated delivery of naproxen in a gastroprotective, antiarthritic/analgesic combination unit dosage form to achieve pain and symptom relief with a reduced risk of developing gastrointestinal damage such as ulcers, erosions and hemorrhages. See abstract. Regarding the amount of naproxen in claim 19, Plachetka defines the effective amount of the NSAID in the specification, col. 6, lines 6 – 11:

> Naproxen is particularly useful when contained in tablets or capsules in an amount from 250 to 500 mg. For naproxen sodium, tablets of about 275 or about 550 mg are typically used. Initial doses of from 100 to 1250 mg, and particularly 350 to 800 mg are also used, with doses of about 550 mg being generally preferred.
> The reference also teaches, "[t]he most preferred NSAID is naproxen in an amount of between 50 mg and 1500 mg, and more preferably, in an amount of between 200 mg and 600 mg. See col. 4, lines 45-47.
> Plachetka further teaches a trilayer tablet that separates an acid inhibitor

contained in a film coat from a core comprising controlled-release naproxen formulated using excipients which control the drug release. The film coat is an enteric coating configured to delay the release of naproxen until the dosage form reaches an environment where the pH is above 3.5, or preferably above 4. See Drawings; col. 3,

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