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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/553,107	09/03/2009	Brian Ault	103526-1 US/NS	5949

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EXAMINER
JUSTICE, GINA CHIEUN YU

ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
07/30/2012	PAPER

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.

Office Action Summary	Application No.	Applicant(s)	
	12/553,107	AULT ET AL.	
	Examiner	Art Unit	
	GINA C. JUSTICE	1617	

-- 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 *08 May 2012*.

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5a) Of the above claim(s) _____ is/are withdrawn from consideration.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.

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).

12)☐ 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

13)☐ 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) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of amendment filed on May 8, 2012. Claims 19, 29, 33, 34, 40, 42 and 45 are now pending.

The previous claim rejection made under 35 U.S.C. § 112, first paragraph, which was indicated in the Office action dated January 5, 2012, is withdrawn in view of the claim amendment.

The obviousness double patenting rejection, indicated in the same Office action, is modified to address claim amendment, particularly the weight amount limitation of naproxen and esomeprazole.

The claim rejection made under 35 U.S.C. § 103 (a) over Plachetka (US 6926907 B2) is modified to address the same claim amendment. The rejection is also modified to address claim 45 which was inadvertently omitted in the previous Office action.

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).

Claims 19, 29, 33, 34, 40, 42 and 45 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-55 of U.S. Patent No. 6926907 B2.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to a method of delivering to a patient (a) an acid inhibitor at a dose effective to raise the gastric pH of said patient to at least 3.5; and b) an NSAID that is released at a pH of 3.5 or greater, wherein esomeprazole is selected as the acid inhibitor and the NSAID is naproxen. See '907, Claims 24-32. The AM and PM dosage of the present claim would have been an obvious method step to utilize the patented invention, as the specification teaches to

administer a naproxen/acid inhibitor according to the prior art invention twice daily. See Examples 9 and 10. Patented claim 53 also describes the multiplayer tablet of instant claim 40. Although the patented claims do not specifically disclose the pharmacokinetic profile of the drugs released from the multilayered tablet, a person of ordinary skill in the art who makes and uses the prior art method according to the teachings would have obviously observed such.

Regarding the amount of naproxen in claim 19, Plachetka teaches,

> [n]aproxen 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.

See col. 6, lines 6 – 11. 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.

Regarding the amount of esomeprazole, the reference teaches using 5-100 mg, with about 40 mg per unit dosage form being preferred. See col. 7, lines 12-13.

Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." See In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). In this case, prior art teaches the ranges of effective and preferred amounts of naproxen and esomeprazole in making unit dosage preparations.

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