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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
22466	7590	01/05/2012	EXAMINER	
ASTRA ZENECA PHARMACEUTICALS LP GLOBAL INTELLECTUAL PROPERTY 1800 CONCORD PIKE WILMINGTON, DE 19850-5437			YU, GINA C	
			ART UNIT	PAPER NUMBER
			1617	
			MAIL DATE	DELIVERY MODE
			01/05/2012	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. 12/553,107	Applicant(s) AULT ET AL.	
	Examiner GINA C. YU	Art Unit 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 ____.
- 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) 19-31, 33, 34, 38-40, 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5a) Of the above claim(s) ____ is/are withdrawn from consideration.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) 19-31, 33, 34, 38-40, 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) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
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 type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19-31, 33, 34, 38-40, 42 and 45 are rejected under 35 U.S.C. 112, first paragraph. The specification, while being enabling for delivering naproxen and esomeprazole as described in the examples to patients suffering from inflammatory diseases, does not reasonably provide enablement for the presently claimed method of delivering the drugs in unspecified routes to unspecified patient population. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The method of claims 19-31, 33, 34, 38 and 39 encompass all types of administration routes in a single entity for drug administration, whereas the specification only enables for oral administration of a multilayer tablet, specifically comprising enteric coated naproxen and non-enteric coated esomeprazole. The scope of the patient population of claims 19-31, 33, 34, 38-40, 42 and 45 also fail to comply with enablement requirement, as at the time of the present invention naproxen was known for treating inflammatory diseases. Applicant provides no other direction or working example in the specification to provide enablement for the full scope of the presently claimed method. Undue experimentations would be necessary to make and use the full scope of the

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present invention in order to determine 1) effective routes, dosage, vehicles, etc., that meet the scope of the presently claimed delivery method; and 2) which user population (e.g., cancer patients) are within the term "a patient in need thereof" as recited the claim.

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

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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 19-31, 33, 34, 38-40, 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 multilayer 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.

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