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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/158,216	05/31/2002	John R. Plachetka	7569/73281	5014

7590      10/20/2004  
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EXAMINER

SPEAR, JAMES M

ART UNIT	PAPER NUMBER
1615	

1615

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

<b>Application No.</b> 10/158,216	<b>Applicant(s)</b> PLACHETKA, JOHN R.	
<b>Examiner</b> James M Spear	<b>Art Unit</b> 1615	

-- 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) 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 the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- 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)  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**

- 4)  Claim(s) 1-54 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5)  Claim(s) 24-49 is/are allowed.
- 6)  Claim(s) 1-6,9-12,21-23 and 50 is/are rejected.
- 7)  Claim(s) 7,8,13-20 and 51-54 is/are objected to.
- 8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

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

- 12)  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-1449 or PTO/SB/08)
- 4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5)  Notice of Informal Patent Application (PTO-152)

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The response and Information Disclosure Statement filed July 22, 2004 have been entered. Claims 1-54 are pending in the application as set forth in the Preliminary Amendment filed October 17, 2003. A complete copy of the IDS filed April 24, 2003 is enclosed and has been considered.

a. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form 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.

2. Claims 1-5, 9, 10, 11, 21, 22 and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Goldman et al US 5,204,118. The claims remain rejected for the reasons set forth in the Office Action mailed April 22, 2004.

3. Applicant's arguments filed July 22, 2004 have been fully considered but they are not persuasive. Applicants state that "all of applicant's claims have requirements not only with respect to the type of active ingredients present in compositions or methods, but also with respect to the way in which active ingredients are delivered in relation to one another". "Specifically claim 1 requires that there be a single unit dosage form containing both an acid inhibitor and an NSAID and that, upon administration to a patient, the dosage form deliver these drugs in a coordinated fashion such that the acid inhibitor is released first and the NSAID is not released until after the gastric ph of the patient is 3.5 or higher. Applicant submits that these characteristics are not disclosed in Goldman." Applicants further state that, "by preventing NSAID from being released until

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the surrounding environment becomes more basic, the pharmaceutical composition defined in claim 1 provides for safer delivery." However claim 1 is a product claim. Applicant's arguments directed to release are more suited for process limitations while claim 1 is a composition. There is nothing in claim 1 that enables the release applicant is referring to. The Goldman reference shows the same components as applicants and the composition would therefore inherently function the same as applicant's. Amending claim 1 to incorporate a polymer coating as set forth in claims 24 and 51-54 would be given favorable consideration in overcoming the prior art rejection.

4. Claims 1, 2, 5, 6, 9-12, 21 and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by Depui et al US 6,613,354 B2. The claims remain rejected for the reasons set forth in the Paper mailed April 22, 2004. Applicants argue that the Depui et al reference, while containing both an NSAID and a proton pump inhibitor, teaches the use of tablet coatings for the purpose of preventing the degradation of gastric inhibitor, not for the purpose of retarding the release of NSAID or protecting the gastrointestinal tract of a patient from damage caused by NSAID released at low ph. Applicant's arguments are not persuasive because applicant's claim 1 does not disclose a coating. The prior art teaches the same elements as applicant's claims. It is the position of this office that since the composition components are the same the dosage form would inherently provide the same release rates and effects on the gastric ph irrespective of the additional coating components.

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5. Claims 7, 8, 13-20 and 51-54 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 1-6, 9-12, 21-23 and 50 are rejected.

Claims 24-49 are allowed.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James M Spear whose telephone number is 571 272 0605. The examiner can normally be reached on Monday thru Friday from 6:30 AM to 3 PM.

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