Ex. 2009

Notice of Allowance dated Nov. 20, 2007

Notice of Allowability	Application No.	Applicant(s)	
	10/741,592	PLACHETKA ET AL.	
	Examiner	Art Unit	
	Sharon E. Kennedy	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *10/10/2007*.

2. ☒ The allowed claim(s) is/are *1-20*.

3. ☐ 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 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)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 10/10/2007
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

Sharon E. Kennedy
Primary Examiner
Art Unit: 1615

DETAILED ACTION

Allowable Subject Matter

Claims 1-20 are allowed.

The following is an examiner's statement of reasons for allowance:

Applicant has filed a supplement Information Disclosure Statement (IDS) on October 10, 2007, including the European Search Report for the corresponding European Patent Application. The European Search Report has been carefully considered. The search report cites 4 references which are indicated as "X"-type references, or are particularly relevant to the European claimed invention. All of these references have been previously cited and considered, with the exception of US 2002/0016348, which is listed for the examiner's consideration on the October 10, 2007 IDS. This reference does not appear to have been previously cited to the examiner, however, it is noted that the corresponding patented version of the '348 application, US 6,384,034, has already been cited and considered. There are no substantive differences between the two versions.

The claims of the present application are directed to a multi-layer pharmaceutical tablet comprising naproxen and a triptan, wherein substantially all of the triptan is in a first layer and substantially all of the naproxen is located within a second layer, arranged in a side by side relationship such that the dissolution of the naproxen occurs independently of the triptan. Claim 19 is directed to a multi-layer pharmaceutical tablet comprising an NSAID and a triptan having the same characteristics (relationship) as the naproxen and triptan combination.

The examiner has already established that it is well-known to form multi-layered pharmaceutical tablets, and that it is also well-known to form a pharmaceutical tablet comprising naproxen and a triptan in combination for preventing migraines. See the non-final rejection dated December 20, 2006. Applicant filed an amendment with a rebuttal on April 5, 2007. See especially pages 6-7 of that response. As stated therein, the claims are limited to one very specific tablet architecture. Applicant argues that an advantage of forming such a tablet is demonstrated in the Examples section of the application. The examiner has very carefully considered these comments.

With specific regard to the additionally filed IDS of October 10, 2007, including the European Search Report, the examiner provides the following comments:

All the references cited therein are merely cumulative to the prior art already considered. Regarding the newly cited patent application by Simitchieva et al., US 2002/0016348, this reference, in the form of the final patent, has already been considered. Simitchieva discloses a combination of a $5HT_{1B/1D}$ agonist (for example rizatriptan, etc.) as disclosed in paragraph [0013], and a COX-2 selective inhibitor such as Celebrex^{R}, Vioxx^{R}, etc, which are NSAIDs, for the treatment of migraines. The drugs may be delivered combined in a single dosage form or delivered via separate dosage forms. A specific example of tablet formulation is provided at [0042]- [0044]. All ingredients are mixed together and subsequently pressed into a tablet. As is evident, this does not disclose or suggest the claimed invention, and is merely cumulative to the references already uncovered.

The international patent to Plachetka, WO 98/06392, is directed to a method and dosage for treating migraines in humans by administering a combination of a long-acting NSAID with a 5-HT agonist. As stated on page 8 of the reference, the 5-HT agonist and NSAID can be administered simultaneously, either in separate formulations or combined in a unit dosage form. Additional information is provided on page 19, lines 14+. Examples are provided on pages 24+. There is no disclosure or suggestion of forming a multi-layer tablet containing the therapeutic agents in separate areas.

The international patent to Jackson, WO 00/06161, is also directed to the prevention of migraine headache reoccurrences (page 3, lines 11-12) comprising administering the combination of a 5-$HT_{1B/1D}$ agonist in various types of dosage forms, including dual-release formulations such as a bi-layer tablet. See also page 8. The reference further states that dual-dash release formulations can also combine the active compound in an immediate-release form with an additional active compound in a pulsed-dash release form. However, there is no indication that the additional agent should be an NSAID or naproxen.

The European patent to Sands, EP 1 051 993, has also been carefully re-considered. Again, while this disclosure is directed to 5-HT receptor agonists in combination with, e.g., an NSAID, essentially this reference is cumulative to the references already considered. Sands, EP-'993 does not disclose or suggest the multi-layer tablet as claimed. See, for example, paragraph [0018], disclosing Table 1 and the various desired triptan medications in combination with the additional agents set forth in Table 3. As stated in EP-'993, the two active agents may be administered together or

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