Title: FIXED COMBINATION DOSAGE FORMS FOR THE TREATMENT OF MIGRAINE

Proportion of Subjects without Pain

Hours

Placebo

PRO-513

(57) Abstract: Therapeutic regimens and dosage forms are disclosed for the treatment of migraine headache. The regimens preferably combine a serotonin receptor agonist, such as sumatriptan, eletriptan or almotriptan, with a fast acting formulation of diclofenac potassium.
A. CLASSIFICATION OF SUBJECT MATTER

IPC: A01N 37/12 (2006.01), 37/44 (2006.01); A61K 9/00 (2006.01), 31.195 (2006.01)

USPC: 424/400.5 14/566

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S.: 424/400.5 14/566

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
<thead>
<tr>
<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>23-33 and 56-60, column 60 lines 10-43, claims 15, 16.</td>
<td>15-33</td>
</tr>
<tr>
<td>Y</td>
<td>U.S. 5,855,907 A (PEYMAN) 05 January 1999 (05.01.1999), column 1, column 2 lines 61-67.</td>
<td>15-33</td>
</tr>
<tr>
<td></td>
<td>special category of cited documents</td>
<td></td>
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</tbody>
</table>

Further documents are listed in the continuation of Box C.

See patent family annex.

Date of the actual completion of the international search: 19 August 2008 (19.08.2008)

Date of mailing: 16 SEP 2008
### Box No. II  Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
   because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: 40 and 41
   because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
   The claims are method claims which depend from compound claims, therefore it is unclear what is being claimed.

3. ☒ Claims Nos.:
   because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

### Box No. III  Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☑ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of any additional fees.

3. ☒ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

**Remark on Protest**

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☒ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.