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(54) Title: TASTE MASKED SUMATRIPTAN TABLETS AND PROCESSES FOR THEIR PREPARATION

(57) Abstract: The technical field of the present invention relates to uncoated, taste masked sumatriptan tablets for oral administration and processes for their preparation. It also relates to wax polished sumatriptan tablets and processes for their preparation.

INTERNATIONAL SEARCH REPORT

PCT/IB 03/02838

A. CLASSIFICATION OF SUBJECT MATTER
 IPC 7 A61K31/4045 A61K9/20 A61K9/28

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)
 IPC 7 A61K

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 practical, search terms used)
 EPO-Internal, WPI Data, PAJ, CHEM ABS Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 01/037816 A (BIOCHEMIE GMBH ;ENTNER REINHARD (AT); JENNEWAIN HERWIG (AT)) 31 May 2001 (2001-05-31) cited in the application the whole document example 1 page 2, lines 4-15	1, 3-17, 23, 46-49, 52-54
X	EP 0 503 440 A (GLAXO GROUP LTD) 16 September 1992 (1992-09-16) the whole document example 1 page 2, lines 32-44 page 3, lines 3-31 page 3, line 5355 -/--	1, 3-17, 23, 46-49, 52-54

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

° Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
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- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *Z* document member of the same patent family

Date of the actual completion of the international search

17 November 2003

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20.02.2004

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INTERNATIONAL SEARCH REPORT

PCT/IB 03/02838

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>& US 5 863 559 A 26 January 1999 (1999-01-26) cited in the application</p> <p>-----</p> <p>WO 01/003672 A (BRUNA ETIENNE ;PROGRAPHARM LAB (FR); CHAUVEAU CHARLES (FR); NOURI) 18 January 2001 (2001-01-18)</p> <p>the whole document example 1 page 1, lines 26-30 page 3, lines 1-26 page 5, lines 16,17 page 11, lines 6-15 claims 1-21</p>	1,3-17, 23, 46-49, 52-54
P,X	<p>-----</p> <p>WO 03/053402 A (COX STEVE R ;HEIMLICH JOHN M (US); JOHN LEE E (US); NOACK ROBERT M) 3 July 2003 (2003-07-03)</p> <p>the whole document page 4, lines 27-34 page 11, lines 6-24 examples 1-3 claims 1-4,8-17</p>	1,3-17, 23, 46-49, 52-54
E	<p>-----</p> <p>WO 03/075893 A (ROSENBERGER VERED ;AQUA OFER (IL); TEVA PHARMA (IL); LERNER E ITZH) 18 September 2003 (2003-09-18)</p> <p>the whole document page 1, lines 12-15 page 4, lines 1-11 page 37; example 5 claims 1,2,4,32-39</p>	1,3-17, 23, 46-49, 52-54
A	<p>-----</p> <p>WO 98/06932 A (ADVANCED ENGINE TECH PTY LTD ;MANTHEY STEVEN CHARLES (AU)) 19 February 1998 (1998-02-19) the whole document</p>	1
A	<p>-----</p> <p>WO 00/48583 A (POZEN INC) 24 August 2000 (2000-08-24) the whole document</p> <p>-----</p>	1

INTERNATIONAL SEARCH REPORT

PCT/IB 03/02838

Box I Observations where certain claims were found unsearchable (Continuation of item 1 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.: 2, 18-22, 28-30
because they relate to subject matter not required to be searched by this Authority, namely:
Although claims 52-54 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
2. Claims Nos.: 2, 18-22, 28-30
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:
see FURTHER INFORMATION sheet PCT/ISA/210
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 II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

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

see additional sheet

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 an additional fee, this Authority did not invite payment of any additional fee.
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.:
1, 3-17, 23, 46-49, 52-54

Remark on Protest

- The additional search fees were accompanied by the applicant's protest.
- No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.1

Claims Nos.: 2,18-22,28-30

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

Continuation of Box I.2

Claims Nos.: 2,18-22,28-30

Claims 2,18-22 and 28-30 do not meet the requirement of Art.6 PCT for lack of clarity because they are directed to a subject-matter (process comprising further the step of polishing the tablet with wax) which is in contradiction with the subject-matter of their independent claims (process of producing uncoated tablet), namely inventions 1 and 3.

The step of wax polishing in claims 2,18-22 and 28-30 belongs in fact to the subject-matter of invention 2, which will be searched when the fees are paid. Therefore even if they depend prima facie on claims 1 or 24, they will not be searched within the frame of the search of the first invention.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.5), should the problems which led to the Article 17(2) declaration be overcome.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1, 3-17, 23, 46-49, 52-54

Process for manufacturing a sumatriptan tablet comprising:
1/ manufacturing granules of sumatriptan with diluents or binders
2/ mixing the obtained granules with other excipients in order to obtain a mixture or an extragranular portion
3/ compressing the product of step 2 in order to form a tablet

2. claims: 37-44, 45, 50-51

Process for manufacturing a sumatriptan dosage form comprising wax polishing the dosage form

3. claims: 24-25, 26-27, 31-36

Process for manufacturing a sumatriptan tablet comprising:
1/ spraying a solution or suspension of sumatriptan onto inert cores, and optionally further spraying a solution of binders or diluents onto the cores having the first layer (claims 26-27)
2/ mixing the product of step 1 with other excipients in order to form a mixture
3/ compressing the mixture to form a tablet

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