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0129117.8 5 December 2001 (05.12.2001) GB
- (71) Applicant (for all designated States except US): **GLAXO GROUP LIMITED** [GB/GB]; Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex UB6 0NN (GB).
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): **BAKER, Robert, William** [GB/GB]; GlaxoSmithKline, Park Road, Ware, Hertfordshire SG12 0DP (GB). **DOW, Alan, David** [GB/GB]; GlaxoSmithKline, Park Road, Ware, Hertfordshire SG12 0DP (GB). **SUMMERS, Simon, John** [GB/GB]; GlaxoSmithKline, Park Road, Ware, Hertfordshire SG12 0DP (GB). **WESTRUP, Julian** [GB/GB]; GlaxoSmithKline, New Frontiers Science Park South, Third Avenue, Harlow, Essex CM19 5AW (GB).
- (74) Agent: **REED, Michael, Antony**; GlaxoSmithKline, 980 Great West Road (CN925.1), Brentford, Middlesex TW8 9GS (GB).
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(54) Title: PHARMACEUTICAL COMPOSITION COMPRISING A 5HT₁ RECEPTOR AGONIST

(57) Abstract: The present invention relates to a pharmaceutical composition for oral administration capable of rapid disintegration and dispersion within the gastrointestinal tract comprising a 5HT₁ receptor agonist as active ingredient, in particular a composition in solid-dosage form that is intended to be swallowed, and methods of treatment of cephalic pain, especially migraine, using such composition.

INTERNATIONAL SEARCH REPORT

International Application No

PCT/EP 02/13715

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61K9/22 A61K9/46 A61K31/00

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, BIOSIS, EMBASE

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 80822 A (PROD ETHIQUES ETHYPHARM S A LABORATOIRES) 1 November 2001 (2001-11-01) example 8	1-26, 28-38
X	WO 99 43306 A (BANYU PHARMA CO LTD) 2 September 1999 (1999-09-02) example 14; table 31	1-18, 20-23, 26,28-37
X	ANONYMOUS: "Zomig-ZMT(TM) Orally Disintegrating Tablets" INTERNET ARTICLE, 'Online! 12 February 2001 (2001-02-12), XP002241488 Retrieved from the Internet: <URL:http://www.fda.gov/cder/foi/label/2001/212311b1.pdf> 'retrieved on 2003-05-15! page 1 page 2, paragraph 3 -page 10, paragraph 1	1-18, 26-33
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 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)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "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.
- "&" document member of the same patent family

Date of the actual completion of the international search

16 May 2003

Date of mailing of the international search report

06/06/2003

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Epskamp, S

INTERNATIONAL SEARCH REPORT

International Application No

PCT/EP 02/13715

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 92 11003 A (GLAXO LAB SA) 9 July 1992 (1992-07-09) cited in the application example 1 claims -----	1-20, 26, 28-33
X	WO 92 15295 A (GLAXO GROUP LTD) 17 September 1992 (1992-09-17) cited in the application examples claims -----	3-19, 26-33
X	WO 98 42344 A (SCHERER LTD R P) 1 October 1998 (1998-10-01) page 12, line 1 - line 5 examples 9,10 -----	1-19, 26, 28-33
X	AHRENS S P ET AL: "Efficacy and safety of rizatriptan wafer for the acute treatment of migraine." CEPHALALGIA, vol. 19, no. 5, June 1999 (1999-06), pages 525-530, XP002241489 ISSN: 0333-1024 abstract page 525, left-hand column, line 17 -right-hand column, paragraph 1 "Results" -----	1-18, 26, 28-33
X	WO 01 39836 A (NATCO PHARMA LTD) 7 June 2001 (2001-06-07) page 4, line 10 - line 12 examples claims -----	1-18, 26, 28-33
X	WO 01 89485 A (HANMI PHARM CO LTD) 29 November 2001 (2001-11-29) examples 6,7 -----	1-18, 26, 28-33

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Present claims 1-38 relate to a dosage form comprising a compound which is defined by its activity, namely "5HT1 receptor agonist". Such claims, in which an active agent is characterized by its activity, can only be clear if instructions, in the form of experimental tests or any testable criteria, are available from the patent documents or from the general knowledge allowing the skilled person to recognise which active agents fall within the functional definition, i.e. the activity, and accordingly within the scope of the claim. Since such instructions are not provided, the concept "5HT1 receptor agonist" is not clear, and therefore the subject-matter of claims 1-38 is not clear (Article 6 PCT). Furthermore, the claims cover all compounds having this activity, whereas the application provides support within the meaning of Article 6 PCT and/or disclosure within the meaning of Article 5 PCT for only a very limited number of such compounds.

In the present case, the claims so lack clarity and support, and the application so lacks disclosure, that a meaningful search over the whole of the claimed scope is impossible.

Consequently, the search has been carried out for those parts of the claims which appear to be clear, supported and disclosed, namely those parts relating to the 5HT1 receptor agonists listed on page 1, lines 13-16 of the application. Also the concept of "5HT1 receptor agonist" was included in the search.

The applicant's attention is drawn to the fact that claims, or parts of 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.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP 02/13715

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

Although claims 30-33 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 composition.
2. Claims Nos.: -
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:

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.:

Remark on Protest

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

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/EP 02/13715

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/EP 02/13715

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