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Declaration under Rule 4.17:

— as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))

Published:

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(54) Title: COMBINATION OF THE PDE4 INHIBITOR ROFLUMILAST AND A TETRAHYDROBIOPTERIN DERIVATIVE

(57) Abstract: The invention describes the use of a PDE4 inhibitor in combination with BH4 or a BH4 derivative for the prevention and/or treatment of respiratory diseases.



WO 2006/120176 A3

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2006/062117

A. CLASSIFICATION OF SUBJECT MATTER INV. A61K31/41 A61K31/505 A61P11/00		
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) 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.
P, Y	WO 2005/041975 A (ALTANA PHARMA AG; HESSLINGER, CHRISTIAN; ULRICH, WOLF-RUEDIGER; SCHUDT) 12 May 2005 (2005-05-12) the whole document -----	1-22
Y	"ROFLUMILAST APTA 2217, B9302-107, BY217, BYK 20869" DRUGS IN R & D, ADIS INTERNATIONAL, AUCKLAND, NZ, vol. 5, no. 3, 2004, pages 176-181, XP008036613 ISSN: 1174-5886 abstract page 180, column 1, paragraph 1 - column 2, paragraph 1 ----- -/--	1-22
☒ Further documents are listed in the continuation of Box C. ☒ See patent family 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. *S* document member of the same patent family		
Date of the actual completion of the international search	Date of mailing of the international search report	
13 November 2006	19/01/2007	
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 Tardi, Christine	

INTERNATIONAL SEARCH REPORT

International application No

PCT/EP2006/062117

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	LIPWORTH B J: "Phosphodiesterase-4 inhibitors for asthma and chronic obstructive pulmonary disease" LANCET 08 JAN 2005 UNITED KINGDOM, vol. 365, no. 9454, 8 January 2005 (2005-01-08), pages 167-175, XP004798081 ISSN: 0140-6736 abstract page 170, column 1, paragraph 2 - page 173, column 1, paragraph 3 -----	1-22
Y	EP 0 908 182 A (SUNTORY LIMITED; DAIICHI SUNTORY PHARMA CO., LTD) 14 April 1999 (1999-04-14) page 1, lines 30-33; claims 1-5 -----	1-22
Y	WO 01/56551 A (UNIVERSITY OF ZURICH; SCHMID, RALPH, A; SCHOEDON, GABRIELE) 9 August 2001 (2001-08-09) page 12, paragraph 3 - page 13, paragraph 1; claims 1,2 page 4, paragraph 3 - page 5, paragraph 2 -----	1-22

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2006/062117

Box 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:

Although claims 16-19 are directed to a method of treatment of the human/animal body (Article 52(4) EPC), the search has been carried out and based on the alleged effects of the compound/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:
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 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 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/EP2006/062117

Patent document cited in search report		Publication date		Patent family member(s)		Publication date
WO 2005041975	A	12-05-2005	AU	2004285300 A1		12-05-2005
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