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(71) Applicant (for all designated States except US): **RATIO-PHARM GMBH** [DE/DE]; Graf-Arco-Strasse 3, 89079 Ulm (DE).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **GIDWANI, Ramesh Matioram** [IN/IN]; Coral 702, Nirmal Lifestyles, L.B.S. Marg, Mulund (West), Mumbai, Maharashtra 400080 (IN). **WAKCHAURE, Vikas S** [IN/IN]; Ekta Residency A-101, Plot No. 14 Sector -6, Khanda Colony, New Panvel, Maharashtra 410206 (IN). **STRIEGEL, Hans-Günter** [DE/DE]; Reiherweg 6, 89143 Blaubeuren (DE). **ALBRECHT, Wolfgang** [DE/DE]; Alfred-Mendler-Weg 25/1, 89075 Ulm (DE).

(74) Agents: **TEIPEL, Stephan** et al.; Prinzregentenstr. 16, 80538 München (DE).

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- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))

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(54) Title: POLYMORPHS OF 4-[4-[[4-CHLORO-3-(TRIFLUOROMETHYL)PHENYL]CARBAMOYLAMINO]PHENOXY]-N-METHYL-PYRIDINE-2-CARBOXAMIDE

(57) Abstract: The present invention relates to polymorphs of 4-[4-[[4-chloro-3-(trifluoromethyl)phenyl]- carbamoylamino]phenoxy]-N-methyl-pyridine-2-carboxamide and pharmaceutical compositions comprising the same.



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INTERNATIONAL SEARCH REPORT

International application No
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A. CLASSIFICATION OF SUBJECT MATTER
INV. C07D213/81
ADD.

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)
C07D

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, CHEM ABS Data, WPI 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 2006/094626 A1 (BAYER HEALTHCARE AG [DE]; SCHUECKLER FRITZ [DE]; WOLLENSCHLAEGER AXEL) 14 September 2006 (2006-09-14)	2-7,16
Y	page 2, line 12 - page 3, line 27; claims 1,3,6,13; example 1 -----	1,8-13, 17,18
X	WO 2008/008733 A2 (ELAN PHARMA INT LTD [IE]; CARTY SARAH [IE]; JENKINS SCOTT [US]; LIVERS) 17 January 2008 (2008-01-17) paragraphs [0037], [0107], [0136]-[0139]claims 1,2,5; example 1 -----	1,8,11, 16-18
X	WO 2006/026501 A1 (BAYER PHARMACEUTICALS CORP [US]; SCHUECKLER FRITZ) 9 March 2006 (2006-03-09) cited in the application claims 2,6,18,19; examples 1-4 ----- -/-	8-10,16



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

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"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

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Name and mailing address of the ISA/

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

Authorized officer

Guspanová, Jana

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International application No
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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	PETIT S ET AL: "The Amorphous State", 1 January 2006 (2006-01-01), 20060101, PAGE(S) 259 - 285, XP002481458, ISBN: 978-3-527-31146-0 the whole document	1,8-13, 17,18
Y	----- WO 2006/034797 A1 (BAYER HEALTHCARE AG [DE]; GRUNENBERG ALFONS [DE]; LENZ JANA [DE]) 6 April 2006 (2006-04-06) cited in the application claims 1-9; figure 2; examples 1-5	14,15
Y	----- WO 2007/038524 A2 (SSCI INC [US]; CHILDS SCOTT [US]) 5 April 2007 (2007-04-05) the whole document	14,15
X,P	----- WO 2009/106825 A1 (CIPLA LTD [IN]; RAO DHARMARAJ RAMACHANDRA [IN]; KANKAN RAJENDRA NARAYA) 3 September 2009 (2009-09-03) claims 1-5,24; examples 1-7	1,8,11, 16
X,P	----- DATABASE CA [Online] CHEMICAL ABSTRACTS SERVICE, COLUMBUS, OHIO, US; 2009, WANG, XUEQING ET AL: "Sorafenib self-microemulsifying drug delivery system for oral medication or intravenous injection, and the preparation method and application thereof", XP002613940, retrieved from STN Database accession no. 2009:1482361 * abstract	1-8,11, 16
X,P	& CN 101 584 661 A (UNIV BEIJING [CN]) 25 November 2009 (2009-11-25) -----	1-8,11, 16

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2010/058006

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.:
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 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:

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 fees, this Authority did not invite payment of 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.

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, 11-13(completely); 16(partially)

Amorphous sorafenib tosylate.

2. claims: 2-7(completely); 16(partially)

Crystalline salts of sorafenib.

3. claims: 8-10(completely); 16(partially)

Composition of amorphous sorafenib free base.

4. claims: 14, 15(completely); 16(partially)

Co-crystal of sorafenib with p-toluenesulphonic acid.

5. claims: 17, 18

Process for preparing amorphous sorafenib or its salt.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/EP2010/058006

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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