

(19) World Intellectual Property Organization  
International Bureau



(43) International Publication Date  
27 August 2009 (27.08.2009)

PCT

(10) International Publication Number  
**WO 2009/104021 A3**

(51) International Patent Classification:  
C07D 403/06 (2006.01) A61K 31/404 (2006.01)

(21) International Application Number:  
PCT/GB2009/050170

(22) International Filing Date:  
20 February 2009 (20.02.2009)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:  
314/KOL/2008 21 February 2008 (21.02.2008) IN

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(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

- with international search report (Art. 21(3))
- 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))

(88) Date of publication of the international search report:  
12 November 2009

(54) Title: NOVEL POLYMORPHS AND PROCESSES FOR THEIR PREPARATION

(57) Abstract: The present invention relates to novel polymorph forms III and IV of sunitinib malate, pharmaceutical compositions comprising the novel polymorphs and the use of the pharmaceutical compositions. The present invention further relates to processes for the preparation of polymorph form I, III and IV of sunitinib malate.



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# INTERNATIONAL SEARCH REPORT

International application No  
PCT/GB2009/050170

**A. CLASSIFICATION OF SUBJECT MATTER**  
INV. C07D403/06 A61K31/404

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 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, BEILSTEIN Data, BIOSIS, CHEM ABS Data, EMBASE, 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 03/016305 A (UPJOHN CO [US]; HAWLEY MICHAEL [US]; FLECK THOMAS J [US]; PRESCOTT STE) 27 February 2003 (2003-02-27) cited in the application the whole document -----	1-25, 68-77
A	WO 01/60814 A (SUGEN INC [US]; TANG PENG CHO [US]; MILLER TODD [US]; LI XIAOYUAN [US]) 23 August 2001 (2001-08-23) cited in the application Claims 49-59; page 24, line 29-page 25, line 8, example 80 ----- -/--	1-25, 68-77

<input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C.	<input checked="" type="checkbox"/> 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. *&* document member of the same patent family	
Date of the actual completion of the international search  <p style="text-align: center; font-weight: bold;">18 May 2009</p>	Date of mailing of the international search report  <p style="text-align: center; font-weight: bold;">18/09/2009</p>
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  <p style="text-align: center; font-weight: bold;">Kirsch, Cécile</p>

## INTERNATIONAL SEARCH REPORT

International application No

PCT/GB2009/050170

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	CAIRA M R: "CRYSTALLINE POLYMORPHISM OF ORGANIC COMPOUNDS" TOPICS IN CURRENT CHEMISTRY, SPRINGER, BERLIN, DE, vol. 198, 1 January 1998 (1998-01-01), pages 163-208, XP001156954 page 164, paragraph 1 and page 165, paragraph 2; page 165, last paragraph to page 166, first paragraph -----	1-25, 68-77
A	BRITAIN ET AL: "Polymorphism in Pharmaceutical Solids passage" POLYMORPHISM IN PHARMACEUTICAL SOLIDS, 1 January 1999 (1999-01-01), pages 235-238, XP002278123 ISBN: 978-0-8247-0237-9 page 236, paragraph 2 -----	1-25, 68-77

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/GB2009/050170

## 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.:

see annex

### 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: 1-25, 68-77 (part)

Sunitinib malate crystalline form III, process for its preparation, pharmaceutical compositions containing it and use thereof for treating cancer.

2. claims: 26-50, 68-77 (part)

Sunitinib malate crystalline form IV, process for its preparation, pharmaceutical compositions containing it and use thereof for treating cancer.

3. claims: 51-67

Process for the preparation of the known sunitinib malate crystalline form I

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/GB2009/050170

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