

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
20 January 2011 (20.01.2011)

PCT

(10) International Publication Number
WO 2011/008495 A3

- (51) **International Patent Classification:**
C12N 9/96 (2006.01) *A61K 38/50* (2006.01)
C12N 9/78 (2006.01)
- (21) **International Application Number:**
PCT/US2010/040205
- (22) **International Filing Date:**
28 June 2010 (28.06.2010)
- (25) **Filing Language:** English
- (26) **Publication Language:** English
- (30) **Priority Data:**
61/221,396 29 June 2009 (29.06.2009) US
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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, CL, 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, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, 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, LR, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AL, 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, SM, 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))
- with sequence listing part of description (Rule 5.2(a))

- (88) **Date of publication of the international search report:**
12 May 2011



WO 2011/008495 A3

(54) **Title:** ARGINASE FORMULATIONS AND METHODS

(57) **Abstract:** Methods and composition for generation of arginase variants with high serum persistence are provided. For example, in certain aspects methods for purifying pegylated arginase are described. Furthermore, the invention provides stabilized arginase multimers or pharmaceutical composition thereof.

A. CLASSIFICATION OF SUBJECT MATTER*C12N 9/96(2006.01)i, C12N 9/78(2006.01)i, A61K 38/50(2006.01)i*

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)

C12N 9/96; C12N 15/55; A61K 38/46; A61K; C12N 15/74; A61K 38/44

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Korean utility models and applications for utility models
Japanese utility models and applications for utility models

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

eKOMPASS(KIPO internal), Pubmed

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|-----------|--|-----------------------|
| X | JENKINSON, C. P. et al. 'Comparative properties of arginases.' Comparative Biochemistry and Physiology. Part B, Biochemistry and Molecular Biology. Vol. 114(1). pp. 107-132 (May 1996) See Tables 1-8. | 1-5,22-24 |
| A | TSUI, S. M. et al. 'Pegylated derivatives of recombinant human arginase(rh Arg1) for sustained in vivo activity in cancer therapy: preparation, characterization and analysis of their pharmacodynamics in vivo and in vitro and action upon hepatocellular carcinoma cell(HCC)' Cancer Cell International. Vol. 9, p. 9 (17 April 2009) See 'Method'. | 1-24 |
| A | WO 04-001048 A1 (BIO-CANCER TREATMENT INTERNATIONAL LIMITED et al.) 31 December 2003 See the abstract. | 1-24 |
| A | US 2005-0244398 A1 (NING CHENG et al.) 03 November 2005 See the abstract. | 1-24 |
| A | WO 03-063780 A2 (CANCER TREATMENTS INTERNATIONAL et al.) 07 August 2003 See the abstract. | 1-24 |

 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 application or patent 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 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

25 MARCH 2011 (25.03.2011)

Date of mailing of the international search report

25 MARCH 2011 (25.03.2011)

Name and mailing address of the ISA/KR


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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:

Invention 1: A stabilized multimeric arginase (claims 1-12, and 22-24)

Invention 2: A method of separating pegylated arginase from unpegylated arginase (claims 13-21)

They are not so linked as to form a single general inventive concept in the sense of Rule 13.1 PCT since there is no technical relationship among inventions involving one or more of the same or corresponding special technical features.

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 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.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/US2010/040205

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International application No.

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