

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization  
International Bureau



(43) International Publication Date  
27 January 2011 (27.01.2011)

PCT

(10) International Publication Number  
**WO 2011/011706 A3**

(51) International Patent Classification:

*A61K 31/66* (2006.01)      *A61P 3/10* (2006.01)  
*A61K 31/675* (2006.01)    *A61P 19/00* (2006.01)  
*A61K 31/67* (2006.01)      *A61P 29/00* (2006.01)  
*A61K 38/10* (2006.01)

(21) International Application Number:

PCT/US2010/043083

(22) International Filing Date:

23 July 2010 (23.07.2010)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

61/228,187	24 July 2009 (24.07.2009)	US
61/251,087	13 October 2009 (13.10.2009)	US
61/251,097	13 October 2009 (13.10.2009)	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))

(88) Date of publication of the international search report:

30 June 2011

(54) Title: METHODS AND COMPOSITIONS FOR TREATING OR PREVENTING AUTOIMMUNE DISEASES USING IMMUNOMODULATORY AGENTS

(57) Abstract: The present invention provides compositions and methods for treating and/or preventing an autoimmune disease comprising administering to a subject in need thereof an effective amount of cyclophosphamide and/or a cyclophosphamide derivative in combination with an additional immunomodulatory agent.



WO 2011/011706 A3

## INTERNATIONAL SEARCH REPORT

International application No.  
**PCT/US2010/043083****A. CLASSIFICATION OF SUBJECT MATTER***A61K 31/66(2006.01)i, A61K 31/675(2006.01)i, A61K 31/67(2006.01)i, A61K 38/10(2006.01)i, A61P 3/10(2006.01)i, A61P 19/00(2006.01)i, A61P 29/00(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)

A61K ; A61P

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), Google &amp; Keywords:cyclophosphamide, treat, autoimmune, anti-CD, antibody, etc.

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2002-0039557 A1 (WHITE, C.) 04 April 2002. See the whole document, especially [0080]-[0081].	142-144
X	US 2008-0213280 A1 (BENYUNES, M. C.) 04 September 2008. See the whole document, especially [0064].	142-144
X	US 2007-0003544 A1 (HANNA, N.) 04 January 2007. See the whole document, especially [0075].	142-144
A	WOFSY, D. AND DAIKH, D. I. "Treatment of autoimmune diseases by inhibition of T-cell costimulation." In Mod. Rheumatol. (2002) Vol.12:1-4. See the whole document, especially page 3, left column.	142-144



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

"&amp;" document member of the same patent family

Date of the actual completion of the international search

27 APRIL 2011 (27.04.2011)

Date of mailing of the international search report

**27 APRIL 2011 (27.04.2011)**

Name and mailing address of the ISA/KR

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**INTERNATIONAL SEARCH REPORT**

International application No.

**PCT/US2010/043083****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.: 1-141  
because they relate to subject matter not required to be searched by this Authority, namely:  
Claims 1-141 pertain to a method for treatment of the human body by therapy, and thus relate to a subject matter which this International Searching Authority is not required, under Article 17(2)(a)(i) of the PCT and Rule 39.1(iv) of the Regulations under the PCT, to search.
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:

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/US2010/043083**

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2002-0039557 A1	04.04.2002	US 2005-0112060 A1 US 6846476 B2	26.05.2005 25.01.2005
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