



- (51) **International Patent Classification:**
A61K 38/43 (2006.01)
- (21) **International Application Number:**
PCT/US2012/035614
- (22) **International Filing Date:**
27 April 2012 (27.04.2012)
- (25) **Filing Language:** English
- (26) **Publication Language:** English
- (30) **Priority Data:**
61/480,961 29 April 2011 (29.04.2011) US
61/617,241 29 March 2012 (29.03.2012) US
- (71) **Applicant (for all designated States except US):** **UNIVERSITY OF WASHINGTON** [US/US]; UW Center for Commercialization, 4311 11th Avenue N.E., Suite 500, Seattle, WA 98105-4608 (US).
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- (74) **Agents:** **SERAFINI, Andrew, T.** et al.; Fenwick & West LLP, 801 California Street, Mountain View, CA 94041 (US).
- (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, QA, RO, RS, RU, RW, 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, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, 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, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).
- Declarations under Rule 4.17:**
— *of inventorship (Rule 4.17(iv))*
- Published:**
— *with international search report (Art. 21(3))*
- (88) **Date of publication of the international search report:**
15 May 2014



WO 2012/149440 A3

(54) **Title:** THERAPEUTIC NUCLEASE COMPOSITIONS AND METHODS

(57) **Abstract:** Hybrid nuclease molecules and methods for treating an immune-related disease or disorder in a mammal, and a pharmaceutical composition for treating an immune-related disease in a mammal.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 12/35614

<p>A. CLASSIFICATION OF SUBJECT MATTER IPC(8) - A61K 38/43 (2012.01) USPC - 424/94.61 According to International Patent Classification (IPC) or to both national classification and IPC</p>																				
<p>B. FIELDS SEARCHED</p> <p>Minimum documentation searched (classification system followed by classification symbols) IPC(8) - A61K 38/43 (2012.01) USPC - 424/94.61</p> <p>Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched</p> <p>Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) PubWEST (PGPB,USPT,USOC,EPAB,JPAB); PubMed (MEDLINE) Search terms: nuclease, ribonuclease, deoxyribonuclease, RNAse, DNase, activity, hybrid, gly, ser, linker, lupus, SLE, cytotoxicity</p>																				
<p>C. DOCUMENTS CONSIDERED TO BE RELEVANT</p> <table border="1"> <thead> <tr> <th>Category*</th> <th>Citation of document, with indication, where appropriate, of the relevant passages</th> <th>Relevant to claim No.</th> </tr> </thead> <tbody> <tr> <td>Y ----- A</td> <td>US 2005/0158307 A1-(SPIES et al.) 21 July 2005 (21.07.2005) para [0007], [0008], [0020], [0025], [0041], [0056], [0087], [0088], [0112]</td> <td>1, 6-7, 9-10, 13-15, 18-22/(1,6-7,9-10,13-15), 28-35 8, 16, 17, 18-22/(8,16,17), 23-26</td> </tr> <tr> <td>Y</td> <td>US 2008/0242845 A1 (LAZAR et al.) 02 October 2008 (02.10.2008) para [0006], [0010], [0018], [0024], [0026], [0184], [0185]</td> <td>1, 6-7, 9-10, 13-15, 18-22/(1,6-7,9-10,13-15), 28-35</td> </tr> <tr> <td>Y</td> <td>US 2011/0081345 A1 (MOORE et al.) 07 April 2011 (07.04.2011) para [0010], [0012], [0148], [0169], [0306]; Fig 1</td> <td>14-15, 18-22/(14,15)</td> </tr> <tr> <td>Y</td> <td>US 2010/0099101 A1 (BEHRENS et al.) 22 April 2010 (22.04.2010) para [0216]</td> <td>21-22/(1,6-7,9-10,13-15)</td> </tr> <tr> <td>A</td> <td>FENTON et al., Anti-dsDNA antibodies promote initiation, and acquired loss of renal Dnase1 promotes progression of lupus nephritis in autoimmune (NZBxNZW)F1 mice. PLoS One. 2009 (published online December 2009), vol 4, no 12, e8474. Especially pg 6, col 1, para 3; pg 6, col 2, para 1</td> <td>36</td> </tr> </tbody> </table>			Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.	Y ----- A	US 2005/0158307 A1-(SPIES et al.) 21 July 2005 (21.07.2005) para [0007], [0008], [0020], [0025], [0041], [0056], [0087], [0088], [0112]	1, 6-7, 9-10, 13-15, 18-22/(1,6-7,9-10,13-15), 28-35 8, 16, 17, 18-22/(8,16,17), 23-26	Y	US 2008/0242845 A1 (LAZAR et al.) 02 October 2008 (02.10.2008) para [0006], [0010], [0018], [0024], [0026], [0184], [0185]	1, 6-7, 9-10, 13-15, 18-22/(1,6-7,9-10,13-15), 28-35	Y	US 2011/0081345 A1 (MOORE et al.) 07 April 2011 (07.04.2011) para [0010], [0012], [0148], [0169], [0306]; Fig 1	14-15, 18-22/(14,15)	Y	US 2010/0099101 A1 (BEHRENS et al.) 22 April 2010 (22.04.2010) para [0216]	21-22/(1,6-7,9-10,13-15)	A	FENTON et al., Anti-dsDNA antibodies promote initiation, and acquired loss of renal Dnase1 promotes progression of lupus nephritis in autoimmune (NZBxNZW)F1 mice. PLoS One. 2009 (published online December 2009), vol 4, no 12, e8474. Especially pg 6, col 1, para 3; pg 6, col 2, para 1	36
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<p><input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/></p>																				
<p>* Special categories of cited documents:</p> <table border="0"> <tr> <td>"A" document defining the general state of the art which is not considered to be of particular relevance</td> <td>"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</td> </tr> <tr> <td>"E" earlier application or patent but published on or after the international filing date</td> <td>"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</td> </tr> <tr> <td>"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)</td> <td>"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</td> </tr> <tr> <td>"O" document referring to an oral disclosure, use, exhibition or other means</td> <td>"&" document member of the same patent family</td> </tr> <tr> <td>"P" document published prior to the international filing date but later than the priority date claimed</td> <td></td> </tr> </table>			"A" document defining the general state of the art which is not considered to be of particular relevance	"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	"E" earlier application or patent but published on or after the international filing date	"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	"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)	"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	"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family	"P" document published prior to the international filing date but later than the priority date claimed									
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"P" document published prior to the international filing date but later than the priority date claimed																				
<p>Date of the actual completion of the international search 03 August 2012 (03.08.2012)</p>		<p>Date of mailing of the international search report 04 SEP 2012</p>																		
<p>Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201</p>		<p>Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774</p>																		

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 12/35614

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 6,716,974 B1 (MACIAG et al.) 06 April 2004 (06.04.2004) col 3, ln 19; Fig 4	17
A	US 2006/0040262 A1 (MORRIS et al.) 23 February 2006 (23.02.2006) para [0018], [0111]; Table 129	8, 16, 17, 18-22/(8,16,17), 23-26
A, P	WO 2011/053982 A2 (LEDBETTER et al.) 05 May 2011 (05.05.2011)	2-5, 11-12, 18-22/(2-5,11-12), 36
A, P	US 2011/0123440 A1 (HANSEN et al.) 26 May 2011 (26.05.2011)	2-5, 11-12, 18-22/(2-5,11-12), 36

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 12/35614

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.: 27
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 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.