



(51) International Patent Classification:

A61K 31/7068 (2006.01) A61M 31/00 (2006.01)  
A61L 29/14 (2006.01) A61P 13/08 (2006.01)  
A61L 29/16 (2006.01) A61P 35/00 (2006.01)  
A61L 31/16 (2006.01) A61P 13/10 (2006.01)  
A61K 9/00 (2006.01)

(21) International Application Number:

PCT/US2013/057841

(22) International Filing Date:

3 September 2013 (03.09.2013)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

61/696,029 31 August 2012 (31.08.2012) 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, BN, 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, 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, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, 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, KM, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

- as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))
- as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))

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:

17 April 2014

(54) Title: DRUG DELIVERY SYSTEMS AND METHODS FOR TREATMENT OF PROSTATE DISEASE COMPRISING GEMCITABINE

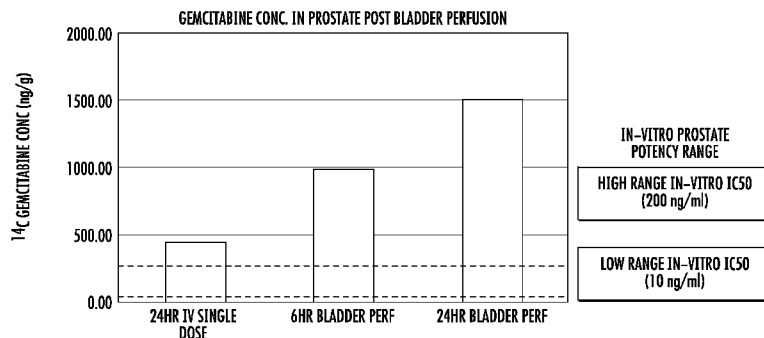


FIG. 7

(57) Abstract: Methods, devices, and medicaments that include gemcitabine are provided for use in the treatment of the prostate disease by locally administering gemcitabine into the bladder of a patient to achieve a sustained concentration of the drug in urine in the bladder sufficient to produce a therapeutic concentration of the drug in the prostate. Gemcitabine may be delivered into the bladder from an intravesical drug delivery device inserted into the bladder, wherein the device continuously releases the drug into the urine in the bladder over an extended period of hours or days.

WO 2014/036556 A3

**INTERNATIONAL SEARCH REPORT**

International application No  
PCT/US2013/057841

**A. CLASSIFICATION OF SUBJECT MATTER**  
 INV. A61K31/7068 A61L29/14 A61L29/16 A61L31/16 A61K9/00  
 A61M31/00 A61P13/08 A61P35/00 A61P13/10  
 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)  
 A61K A61L A61M

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 practicable, search terms used)  
 EPO-Internal, 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	US 2012/203203 A1 (LEE HEEJIN [US] ET AL) 9 August 2012 (2012-08-09) cited in the application abstract; claims 21-36 page 14, lines 1-3,8, paragraphs 180,186 -----	1-11, 15-26
A	US 2010/015200 A1 (MCCLAIN JAMES B [US] ET AL) 21 January 2010 (2010-01-21) examples 18,20 paragraphs [0321] - [0324] -----	1-11, 15-26
A	EP 1 913 962 A1 (PERELSON OPHIR [US]) 23 April 2008 (2008-04-23) abstract; claims 1-2,; examples 1-17 ----- -/--	1-11, 15-26

Further documents are listed in the continuation of Box C.

See patent family annex.

\* Special categories of cited documents :

<p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier application or patent but published on or after the international filing date</p> <p>"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)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p>	<p>"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</p> <p>"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</p> <p>"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</p> <p>"&amp;" document member of the same patent family</p>
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Date of the actual completion of the international search  7 February 2014	Date of mailing of the international search report  14/02/2014
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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  Madalinska, K
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## INTERNATIONAL SEARCH REPORT

International application No

PCT/US2013/057841

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>MIKE D. SHELLEY ET AL: "Intravesical gemcitabine therapy for non-muscle invasive bladder cancer (NMIBC): a systematic review", BJU INTERNATIONAL, vol. 109, no. 4, 7 February 2012 (2012-02-07), pages 496-505, XP055088345, ISSN: 1464-4096, DOI: 10.1111/j.1464-410X.2011.10880.x the whole document</p> <p style="text-align: center;">-----</p>	1-11, 15-26

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US2013/057841

## 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.:

6-11, 22-26(completely); 1-5, 15-21(partially)

### 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: 6-11, 22-26(completely); 1-5, 15-21(partially)

A medicament comprising gemcitabine for use in the treatment of prostate disease by locally administering the gemcitabine into the bladder of a patient, that is delivered into the bladder from an intravesical drug delivery device

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2. claims: 12, 13(completely); 1-5, 15-21(partially)

A medicament comprising gemcitabine for use in the treatment of prostate disease by locally administering the gemcitabine into the bladder of a patient, that is delivered into the bladder from a coating substance applied to the bladder

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3. claims: 14(completely); 1-5, 15-21(partially)

A medicament comprising gemcitabine for use in the treatment of prostate disease by locally administering the gemcitabine into the bladder of a patient, that is delivered into the bladder by pumping a liquid form of the gemcitabine to the bladder

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# INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2013/057841

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2012203203	A1	09-08-2012	CA 2825399 A1 09-08-2012
			CN 103379902 A 30-10-2013
			EP 2670398 A1 11-12-2013
			US 2012203203 A1 09-08-2012
			WO 2012106714 A1 09-08-2012
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US 2010015200	A1	21-01-2010	NONE
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EP 1913962	A1	23-04-2008	EP 1913962 A1 23-04-2008
			WO 2008087488 A2 24-07-2008
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