

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
13 September 2007 (13.09.2007)

PCT

(10) International Publication Number
WO 2007/103809 A3

(51) International Patent Classification:
A61M 1/30 (2006.01)

(21) International Application Number:
PCT/US2007/063209

(22) International Filing Date: 2 March 2007 (02.03.2007)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/778,750 3 March 2006 (03.03.2006) US
60/802,316 19 May 2006 (19.05.2006) US

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(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, 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, 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, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

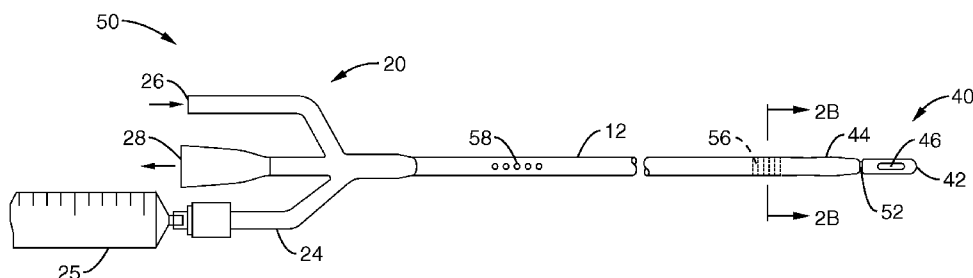
(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, 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

(88) Date of publication of the international search report:
17 July 2008

(54) Title: SYSTEM AND METHOD FOR URINARY TRACT CELL COLLECTION, DIAGNOSIS, AND CHEMOTHERAPY



(57) Abstract: A system and method delivers and collects a wash medium into a lumen of the urinary tract system. Isolated saline delivery washes cells from a urethra that are collected for cancer diagnosis. BCG is delivered for local chemotherapy. The isolated delivery and collection is from a region bound by a distal occlusion and proximal occlusion. Inflatable balloons provide the occlusion and or a penis clamp may be used. The two balloons may telescope relative to each other. A balloon inflation lumen may collapse a valve membrane to occlude distal flow of infused fluid to only proximal of the balloon.

WO 2007/103809 A3

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 07/63209

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61M 1/30 (2008.01)

USPC - 604/19

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)

IPC8 : A61M 1/30 (2008.01)

USPC : 604/19

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

IPC8 : A61M 1/00, A61M 5/00, A61M 25/00, A61M 25/10, A61M 25/14 (2008.01)

USPC : 604/48, 604/93.01, 604/96.01, 604/101.01, 604/101.03, 604/101.05, 604/102.01, 604/517, 604/544

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

PubWEST (PGPB,USPT,EPAB,JPAB), Google Scholar

irrigate, wash, infuse, collect, lumen, penile, penis, clamp, balloon, catheter, transurethral, urethral, urinary tract, cell, cancer, bcg

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2002/0026209 A1 (HUNG) 28 February 2002 (28.02.2002) see especially para [0025], [0026], [0028], [0029], [0031]-[0035], [0038], [0040]-[0045], [0048], [0049], figs 2-6	1-4, 6-9, 11, 15-18, 21, 22, 27-34, 36, 37, 46-48, 58, 59, 69-71, 73, 75-77, 79, 83-86, 89, 90, 92-96, 98 and 100
Y		12-14, 19, 20, 23, 24, 35, 53-57, 72, 78, 99 and 102-110
Y	US 6,102,888 A (WALKER) 15 August 2000 (15.08.2000) see especially col 6, ln 1-19, col 4, ln 1-7, figs 7 and 9	12-14, 102-110
Y	US 4,655,746 A (DANIELS et al) 7 April 1987 (07.04.1987) see especially col 2, ln 10-47	19, 20, 23, 24
Y	US 2005/0196795 A1 (SIEGLER et al) 8 September 2005 (08.09.2005) see especially para [0041]	35
Y	US 2005/0054994 A1 (CIOANTA et al) 10 March 2005 (10.03.2005) see especially para [0061], [0075], [0077], [0105]	53-57
Y	US 3,977,408 A (MacKEW) 31 August 1976 (31.08.1976) see especially col 2, ln 48-56, col 3, ln 16-30, fig 2	72, 78
Y	US 2002/0188246 A1 (HAYNER et al) 12 December 2002 (12.12.2002) see especially para [0010]	99

☐ Further documents are listed in the continuation of Box C.

* 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 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

12 March 2008 (12.03.2008)

Date of mailing of the international search report

14 APR 2008

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents

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Facsimile No. 571-273-3201

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PCT OSP: 571-272-7774

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 07/63209

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:

- Group 1: Claims 1-4, 6-9, 11-24, 27-37, 46-48, 53-59, 69-73, 75-79, 83-86, 89, 90, 92-96, 98-100, 102-110 directed to methods and a medical device system for collecting cells from an isolated luminal section for analysis.
Group 2: Claims 5, 10-14, 21-24, 37, 46-48, 53-57, 69, 70, 87-89, 91-99, 101, 111-114 directed to methods and a medical device system for treating an isolated luminal section.
Group 3: Claims 1-4, 25-26, 38-41, 73-75, 77, 79, 80-82 directed to a diagnostic system.
Group 4: Claims 1-5, 17, 18, 21, 22, 42-45, 49-52, 60-68 directed to a catheter or balloons that comprise an elastomer.

Medical device systems and methods for treating an isolated luminal section or for collecting cells therefrom for analysis were known in the art (US 4,655,746 A (DANIELS et al.) 07 Apr 1987 (07.04.1987), Fig. 6, abstract, col 7, ln 48 to col 8, ln 19) and therefore similarity to such a device and methods can not provide the special technical feature required for unity of invention. Furthermore, the claims of Group 3 require the special technical feature of a diagnostic system for analyzing the collected cells, which is not required for the claims of Groups 1, 2 or 4. The claims of Group 4 require the special technical feature of catheter or balloons that comprise elastomers, which is not required for the claims of Groups 1-3.

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.:
1-4, 6-9, 11-24, 27-37, 46-48, 53-59, 69-73, 75-79, 83-86, 89, 90, 92-96, 98-100 and 102-110

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.