(19) World Intellectual Property Organization

International Bureau





(43) International Publication Date 4 May 2006 (04.05.2006)

(10) International Publication Number WO 2006/047198 A3

(51) International Patent Classification:

A61M 5/00 (2006.01) A61K 9/00 (2006.01) A61M 5/14 (2006.01) A61B 19/00 (2006.01) A61M 5/142 (2006.01)

(21) International Application Number:

PCT/US2005/037684

(22) International Filing Date: 17 October 2005 (17.10.2005)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

60/622,482 26 October 2004 (26.10.2004) US

(71) Applicant (for all designated States except US): CAR-ITAS ST. ELIZABETH MEDICAL CENTER OF BOSTON, INC. [US/US]; 736 Cambridge Street, Boston, MA 02135 (US).

(72) Inventors; and

- (75) Inventors/Applicants (for US only): LOSORDO, Douglas, W. [US/US]; 12 Brooks Street, Winchester, MA 01890 (US). KISHORE, Raj [IN/US]; 14 Sherwood Drive, Westford, MA 01886 (US).
- (74) Agents: BUCHANAN, Robert, L. et al.; Edwards & Angell, LLP, P.O. Box 55874, Boston, MA 02205 (US).

- (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, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, 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, 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: 31 May 2007

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: COMPOSITION AND METHOD FOR USING A CYTOKINE TO TREAT RESTENOSIS

(57) Abstract: The present invention provides devices, including stents and vascular catheters, comprising interleukin-10, for the treatment of restenosis and intimal hyperplasia associated with acute vascular injury. Also provided are methods for treating restenosis and preventing vascular obstruction.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US05/37684

A. CLA IPC(8):	SSIFICATION OF SUBJECT MATTER A61M 5/00(2006.01),5/14(2006.01),5/142(2006.	01); A61K 9/00 (2006.01); A61B 19/00 (200	06.01)	
USPC: 604/8,9;604/890.1,891.1,892.1;128/899 According to International Patent Classification (IPC) or to both national classification and IPC				
B. FIEL	DS SEARCHED			
Minimum documentation searched (classification system followed by classification symbols) U.S.: 604/8,9; 604/890.1, 891.1,892.1; 128/899				
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) EAST, PUBMED				
C. DOC	UMENTS CONSIDERED TO BE RELEVANT			
Category *	Citation of document, with indication, where a	appropriate, of the relevant passages	Relevant to claim No.	
X	US 2002/0128599 A1 (CORMIER et al) 12 September 2002 (12.09.2002), paragraphs 17-18, 67-68, 21, and 40.		1-3	
X	US 2002/0090388 A1 (HUMES et al) 11 July 2002 (07.11.2002), paragraphs 11, 20, 25, 27, 75, and Figures 1-10.			
Further	r documents are listed in the continuation of Box C.	See patent family annex.		
"A" documen	Special categories of cited documents: It defining the general state of the art which is not considered to be of 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 ap	plication or patent published on or after the international filing date	"X" document of particular relevance; the cl considered novel or cannot be considered		
	t which may throw doubts on priority claim(s) or which is cited to the publication date of another citation or other special reason (as)	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 document as the contract of the combined with one or more other such documents.		
"O" documen	t referring to an oral disclosure, use, exhibition or other means	combined with one or more other such documents, such combination being obvious to a person skilled in the art		
	t published prior to the international filing date but later than the late claimed	"&" document member of the same patent family		
-		Date of mailing of the international search report		
03 February 2007 (03.02.2007) Name and mailing address of the ISA/US Authorized officer				
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450		Cherie Woodward White Sack of		
Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201 Telephone No. 571 272-1600				

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US05/37684

Box No. I			
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.: 4-21,25-59,60-72 (p. 40-41), 64-65 (p. 41), 67-68, 70-73, 77-83 because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).		
Box No. I	Observations where unity of invention is lacking (Continuation of item 3 of first sheet)		
This Internation Please See	tional Searching Authority found multiple inventions in this international application, as follows: Continuation Sheet		
1.	As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims. As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of any additional fees. 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. Remark on	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.: 1-3 Protest		

Form PCT/ISA/210 (continuation of first sheet(2)) (April 2005)

International application No. INTERNATIONAL SEARCH REPORT PCT/US05/37684 BOX III. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. Group I, claims 1-3, drawn to a device suitable for implantation in a patient and a method of use. Group II, claims 22-24, drawn to a vascular catheter and method of use. Group III, claim 66 [p.41], drawn to a biosynthetic graft material and method of use. Group IV, claim 69, drawn to a method of treating or preventing vascular occlusion or obstruction comprising contacting the vascular lumen with IL-10. Group V, claims 74-76, drawn to a method of preventing blood vessel obstruction after blood vessel grafting. It is noted that there is a typographical error listing two sets of claims 64-72. The page numbers from the claim listing in the disclosure have been cited for ease of reference The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: claim 1 is anticipated by CORMIER et al., US PreGrant Publication US 2002/0128599 A1 (published 12 September 2002). Cormier et al., teach a device and method for the percutaneous delivery of a biologically active agent. A device comprising a body having open ends, a sidewall and a polymer on at least a part of the surface of the sidewall is taught as a hollow needle at paragraphs 67 and 68. See also paragraphs 17-18. Microprojections are taught at paragraph 21. Coatings of IL-10 are taught at paragraph 40. As such, the remaining claims lack the same or corresponding technical feature.

Claims 4-21, 25-59, 60-72 (pp. 40-41), 64-65 (p. 41), 67-68, 70-73, and 77-83 are improperly dependent claims