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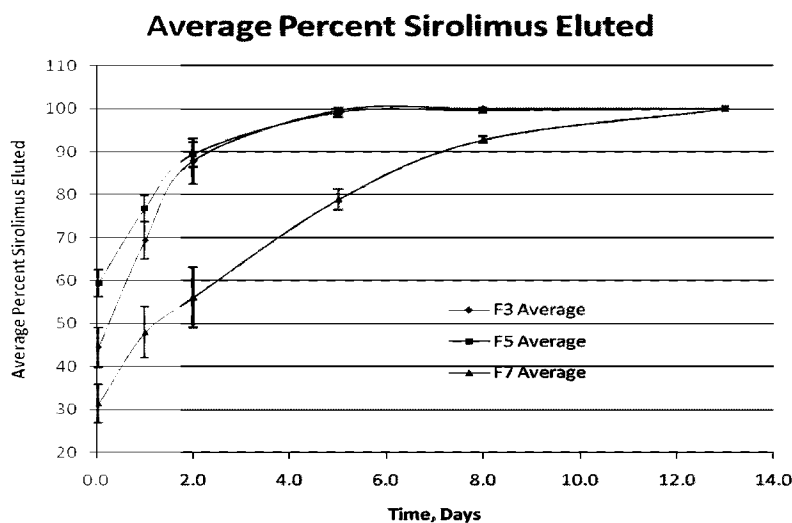
Declarations under Rule 4.17:

— as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))

[Continued on next page]

(54) Title: DRUG DELIVERY MEDICAL DEVICE

FIGURE 1



(57) Abstract: Provided is a coated implantable medical device, comprising: a substrate; and a coating disposed on the substrate, wherein the coating comprises at least one polymer and at least one pharmaceutical agent in a therapeutically desirable morphology and/or at least one active biological agent and optionally, one or more pharmaceutical carrying agents; wherein substantially all of pharmaceutical agent and/or active biological agent remains within the coating and on the substrate until the implantable device is deployed at an intervention site inside the body of a subject and wherein upon deployment of the medical device in the body of the subject a portion of the pharmaceutical agent and/or active biological agent is delivered at the intervention site along with at least a portion of the polymer and/or a at least a portion of the pharmaceutical carrying agents.

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— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))* — *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))*

Published:

— *with international search report (Art. 21(3))*

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A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61F 2/06 (2011.01)

USPC - 623/1.42

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)
USPC - 623/1.42Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC - 623/1.42, 1.46; IPC(8) - A61F 2/06 (2011.01)Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PubWEST(USPT,PGPB,EPAB,JPAB); Google Scholar. Search Terms: balloon, coating, release, expand, inflate, polyarginine, binder, binding agent, sirolimus, layer, active, agent, ingredient, material, compound, particle size, lactic, glycolic, acid, copolymer, stent, electrostatic, vein, artery, lumen, luminal, endoluminal, ultraviolet, visible, spectro

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2010/0015200 A1 (MCCLAIN et al.) 21 January 2010 (21.01.2010), abstract; paras [0024]-[0025], [0049], [0218], [0613]-[0614], [0852]-[0853]	1-27, 52-55
Y	US 2010/0063570 A1 (PACETTI et al.) 11 March 2010 (11.03.2010), abstract; paras [0050], [0167]	1-27, 52-55
Y	US 2003/0232014 A1 (BURKE et al.) 18 December 2003 (18.12.2003), para [0045]	3, 8, 16, 21
Y	US 2009/0068266 A1 (RAHEJA et al.) 12 March 2009 (12.03.2009), paras [0001], [0009]	4-5, 17-18
Y	US 5,350,627 A (NEMPHOS et al.) 27 September 1994 (27.09.1994), abstract; col 3, ln 20-28	7, 20
Y	US 2009/0285974 A1 (KERRIGAN) 19 November 2009 (19.11.2009), para [0015]	9, 22-23
Y	US 5,562,922 A (LAMBERT) 08 October 1996 (08.10.1996), col 9, ln 7-15	10-11, 24-25
Y	US 2009/0231578 A1 (LING et al.) 17 September 2009 (17.09.2009), para [0037]	12-13, 26-27

 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

24 January 2012 (24.01.2012)

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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:

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. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I: claims 1-27, 52-55, drawn to a medical device comprising: a balloon; and a coating on at least a portion of the balloon, wherein the coating comprises an active agent and a binding agent, and wherein the device releases at least 3% of the active agent to artery five minutes after expansion of the balloon in the artery in vivo.

Group II: claims 28-41, 52-59, drawn to a medical device comprising: an invertable balloon; and a coating on an abluminal side of the invertable balloon, wherein the coating comprises an active agent and a binding agent, and wherein the device releases at least 3% of the active agent to artery upon inflation of the balloon in vivo.

-----Please see continuation 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 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.:
1-27, 52-55

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

01/044263/09.02.2012

International application No.

PCT/US 11/44263

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2006/0210638 A1 (LIVERSIDGE et al.) 21 September 2006 (21.09.2006), para [0157]	23

Box III (cont.) - Observations where unity of invention is lacking.

Group III: claims 42-51, 52-59, drawn to a medical device comprising: a balloon; and a coating on the balloon, and an occluder, wherein the coating comprises an active agent and a binding agent, and wherein the device releases at least 3% of the active agent to artery upon inflation of the balloon in vivo.

The inventions listed as Groups I through III 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:

The inventions of Groups I-II do not include the inventive concept of providing an occluder, as required by Group III.

The inventions of Group I do not include the inventive concept of an invertable balloon, and a coating on an abluminal side of the invertable balloon, as required by Group II.

The inventions of Groups I-III share the technical feature of a medical device or a method comprising a balloon; and a coating on at least a portion of the balloon, wherein the coating comprises an active agent and a binding agent, wherein the device releases at least 3% of the active agent to artery upon inflation of the balloon in vivo. However, this shared technical feature does not represent a contribution over prior art as being anticipated by US 2003/0208096 A1 to Tam et al. (hereinafter 'Tam'). Tam discloses Claim 2, a medical device comprising a balloon (abstract and para [0020]); and a coating on at least a portion of the balloon (para [0020]). This isotope layer may be bound directly to, or impregnated within, the wall of the balloon) wherein the coating comprises an active agent and a binding agent (para [0014], the isotope layer is the active agent and the substrate layer is the binding agent), wherein the device releases at least 3% of the active agent to artery upon inflation of the balloon in vivo (para [0148], the radiation delivery and balloon dilatation catheter is utilized to simultaneously dilate a stenosis in a vessel and deliver a treating dose of radiation; para [0147], 'If delivery time greatly in excess of one or two minutes' indicates that the delivery time is usually one or two minutes). As said composition was known in the art at the time of the invention, this cannot be considered a special technical feature that would otherwise unify the groups.

Groups I through III therefore lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.