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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: ZOTAROLIMUS-CONTAINING DRUG DELIVERY SYSTEMS FOR IMPLANTATION INTO A BODY LUMEN OF A SUBJECT

(57) Abstract: Systems and compositions comprising zotarolimus that are safer, more effective and produce less inflammation than rapamycin and paclitaxel systems are disclosed. Medical devices comprising supporting structures capable of containing or supporting a pharmaceutically acceptable carrier or excipient, which carrier or excipient can contain one or more therapeutic agents or substances, with the carrier including a coating on the surface thereof, and the coating having the therapeutic compounds, including, for example, drugs. Supporting structures for the medical devices that are suitable for use in this invention include coronary stents, peripheral stents, catheters, arterio-venous grafts, by-pass grafts, and drug delivery balloons used in the vasculature. These compositions and systems can be used in combination with other drugs, including anti-proliferative agents, anti-platelet agents, anti-inflammatory agents, anti-thrombotic agents, cytotoxic drugs, agents that inhibit cytokine or chemokine binding, cell de-differentiation inhibitors, anti-lipaedemic agents, matrix metalloproteinase inhibitors, cytostatic drugs, or combinations of these and other drugs.

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## INTERNATIONAL SEARCH REPORT

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## A. CLASSIFICATION OF SUBJECT MATTER

INV. A61K9/00 A61K31/00 A61F2/06 A61L31/16 A61L29/00  
A61L27/00

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 A61F A61L

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 practical, search terms used)

EPO-Internal, WPI Data, EMBASE, BIOSIS, CHEM ABS Data

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages                                                                                                   | Relevant to claim No. |
|-----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| X         | WO 2005/092406 A (ADVANCED CARDIOVASCULAR SYSTEM [US]; GLAUSER THIERRY [US]; PACETTI STE) 6 October 2005 (2005-10-06)<br>claims 1-70<br>page 14, line 28 - page 14, line 33<br>----- | 1-88                  |
| X         | US 2005/271700 A1 (DESNOYER JESSICA R [US] ET AL) 8 December 2005 (2005-12-08)<br>claims 1-45<br>-----                                                                               | 1-88                  |
| X         | US 2005/245637 A1 (HOSSAINY SYED F A [US] ET AL) 3 November 2005 (2005-11-03)<br>claims 1-59<br>-----<br>-/--                                                                        | 1-88                  |

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

☒ See patent family annex.

\* 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 document 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.

\*Z\* document member of the same patent family

Date of the actual completion of the international search

13 September 2007

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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages                                                                                                                                                                                                                  | Relevant to claim No.              |
|-----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|
| X         | ANONYMOUS: "Randomised comparison of zotarolimus eluting and sirolimus-eluting stents in patients with coronary artery disease (ENDEAVOUR III)"<br>JOURNAL OF AMERICAN COLLEGE OF CARDIOLOGY, vol. 46, no. 11,<br>6 December 2005 (2005-12-06), pages<br>CS5-CS6, XP009089338<br>the whole document | 1-19,<br>24-42,<br>47-68,<br>73-88 |
| P,X       | -----<br>WO 2006/102359 A (ABBOTT LAB [US]; CROMACK<br>KEITH R [US]; TONER JOHN L [US]; BURKE<br>SANDRA) 28 September 2006 (2006-09-28)<br>claims 1-161<br>examples 1-3<br>table 3                                                                                                                  | 1-88                               |
| P,X       | -----<br>WO 2007/024492 A (MEDTRONIC VASCULAR INC<br>[US]; CHEN PEIWEN [US]; CHENG MINGFEI<br>[US]; UDI) 1 March 2007 (2007-03-01)<br>claims 1-23                                                                                                                                                   | 1-88                               |
| E         | -----<br>WO 2007/076288 A (ABBOTT LAB [US];<br>HAUENSTEIN DALE [US])<br>5 July 2007 (2007-07-05)<br>claims 1-47<br>paragraph [0067]                                                                                                                                                                 | 1-88                               |
| E         | -----<br>WO 2007/046935 A (ABBOTT LAB [US]; BURKE<br>SANDRA E [US]; CROMACK KEITH R [US]; MACK<br>MATTH) 26 April 2007 (2007-04-26)<br>claims 1-60                                                                                                                                                  | 1-88                               |

## INTERNATIONAL SEARCH REPORT

International application No.  
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### Box 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:  
  
Although claims 73-75 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
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 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 an additional fee, this Authority did not invite payment of any additional fee.
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.
- ☐ No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

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| Patent document<br>cited in search report | Publication<br>date | Patent family<br>member(s)           | Publication<br>date      |
|-------------------------------------------|---------------------|--------------------------------------|--------------------------|
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| US 2005245637 A1                          | 03-11-2005          | EP 1755698 A2<br>WO 2005110508 A2    | 28-02-2007<br>24-11-2005 |
| WO 2006102359 A                           | 28-09-2006          | NONE                                 |                          |
| WO 2007024492 A                           | 01-03-2007          | NONE                                 |                          |
| WO 2007076288 A                           | 05-07-2007          | US 2007141104 A1                     | 21-06-2007               |
| WO 2007046935 A                           | 26-04-2007          | WO 2007047416 A2<br>WO 2007047473 A2 | 26-04-2007<br>26-04-2007 |