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

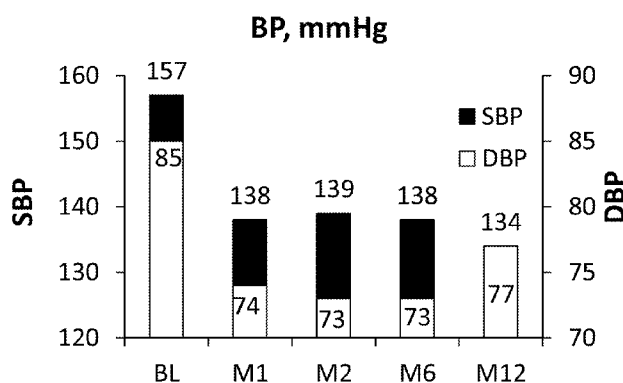
Published:

- 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))

[Continued on next page]

(54) Title: POTASSIUM-BINDING AGENTS FOR TREATING HYPERTENSION AND HYPERKALEMIA

FIG. 9



(57) Abstract: The present invention generally relates to methods of treating hypertension (HTN) in patients in need thereof wherein the patient optionally further suffers from chronic kidney disease (CKD) or Type II diabetes mellitus (T2DM). The invention also relates to methods of treating hyperkalemia in a patient in need thereof, wherein the patient suffers from CKD, T2DM or HTN and are optionally being treated with an effective amount of a renin-angiotensin-aldosterone system (RAAS) agent. The invention also relates to methods of treating kidney disease in a patient in need thereof, wherein the patient is optionally being treated with an effective amount of a renin-angiotensin-aldosterone system (RAAS) agent. The methods can comprise administering an effective amount of a potassium-binding agent to the patient to lower the patient's blood pressure and/or increase or stabilize the patient's kidney function.

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INTERNATIONAL SEARCH REPORT

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|--|--|------------------------------|--|--|
| A. CLASSIFICATION OF SUBJECT MATTER INV. A61K31/78 A61K31/7004 A61K33/06 A61P9/12 A61P13/12 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 A61P | | | | |
| 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. | | |
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| <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border: none;"><input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C.</td> <td style="width: 50%; border: none;"><input checked="" type="checkbox"/> See patent family annex.</td> </tr> </table> | | | <input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C. | <input checked="" type="checkbox"/> See patent family annex. |
| <input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C. | <input checked="" type="checkbox"/> See patent family annex. | | | |
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| "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 | Date of mailing of the international search report | | | |
| 25 August 2014 | 01/09/2014 | | | |
| 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 Nyeki, Agnes | | | |

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INTERNATIONAL SEARCH REPORT

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| C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT | | |
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| A | <p>MARK C HOUSTON: "The Importance of Potassium in Managing Hypertension", CURRENT HYPERTENSION REPORTS, CURRENT SCIENCE INC, NEW YORK, vol. 13, no. 4, 15 March 2011 (2011-03-15), pages 309-317, XP019921524, ISSN: 1534-3111, DOI: 10.1007/S11906-011-0197-8 the whole document</p> <p>-----</p> | 1-137 |
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| A | <p>WO 2005/094384 A2 (ILYPSA INC [US]; ALPERN ROBERT [US]; BUYSE JERRY M [US]; CHANG HAN TI) 13 October 2005 (2005-10-13) pages 4-5, paragraph 15 pages 30-34; examples 2,3 claims</p> <p>-----</p> | 1-137 |
| X | <p>BUYSE J M ET AL: "PEARL-HF: Prevention of hyperkalemia in patients with heart failure using a novel polymeric potassium binder, RLY5016", FUTURE CARDIOLOGY, FUTURE MEDICINE LTD., LONDON, GB, vol. 8, no. 1, January 2012 (2012-01), pages 17-28, XP009177939, ISSN: 1479-6678, DOI: 10.2217/FCA.11.71 the whole document</p> <p>-----</p> | 73-83, 85-109, 112-137 |
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International application No
PCT/US2013/063921

| C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT | | |
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| E | WO 2014/015240 A1 (SORBENT THERAPEUTICS INC [US]) 23 January 2014 (2014-01-23) pages 2-4, paragraph 5-13 pages 171-172, paragraph 620 pages 224-227; example 21 page 229; example 26 page 233; example 30 claims ----- | 1-137 |

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PCT/US2013/063921

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.:

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: 1-72(completely); 83-137(partially)

A potassium-binding agent for use in treating hypertension.

2. claims: 73-82(completely); 83-137(partially)

A potassium-binding agent for use in treating chronic kidney disease, in particular hyperkalemia in a chronic kidney disease patient.

INTERNATIONAL SEARCH REPORT

Information on patent family members

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International application No

PCT/US2013/063921

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
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| ----- WO 2014015240 ----- | A1 | 23-01-2014 | NONE |