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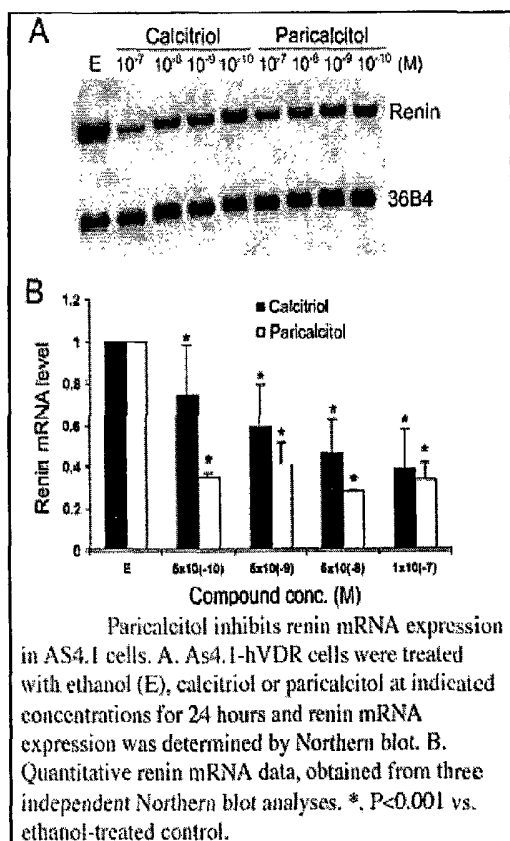
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KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD,
MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG,
PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM,
TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM,
ZW.

[Continued on next page]

(54) Title: USE OF A VITAMIN D RECEPTOR ACTIVATOR OR A VITAMIN D ANALOG TO TREAT KIDNEY DISEASE



(57) Abstract: The present invention relates to the use of Vitamin D receptor activator or Vitamin D analog, preferably paricalcitol, to treat, prevent and delay progression of kidney disease. According to one embodiment, the compounds are provided in a sustained release pharmaceutical composition. According to another embodiment, the Vitamin D receptor activator or Vitamin D analog is combined with at least one of an angiotensin converting enzyme inhibitor, an angiotensin (II) receptor (I) blocker or an aldosterone blocker.



(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, IT, LU, 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).

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INTERNATIONAL SEARCH REPORT

International Application No
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A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61K31/592 A61K31/593 A61K45/06 A61P13/12 A61K9/00
A61K9/70

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)

IPC 7 A61K

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, PAJ, MEDLINE, BIOSIS, EMBASE, SCISEARCH, 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	US 5 597 815 A (SLATOPOLSKY EDUARDO ET AL) 28 January 1997 (1997-01-28) column 1, line 64 - column 2, line 2 column 2, line 26 - line 51 column 4, line 19 - line 22 column 4, line 45 - line 49 claims 1,4,8-10 -----	1,3,4, 10-12, 18-20
X	US 4 230 701 A (HOLICK MICHAEL F ET AL) 28 October 1980 (1980-10-28) column 3, line 5 - line 34 column 4, line 47 - column 5, line 28 column 5, line 48 - line 55 column 6, line 56 - line 60 ----- -/--	1,2,10, 11,18,19

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

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

7 December 2004

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INTERNATIONAL SEARCH REPORT

International Application No

PCT/US2004/024517

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>US 5 614 513 A (KNUTSON JOYCE C ET AL) 25 March 1997 (1997-03-25)</p> <p>column 1, line 10 - line 14 column 2, line 48 - column 3, line 7 column 4, line 26 - line 34 column 8, line 23 - line 46 example 9</p> <p>-----</p>	1,2,5, 10,11, 13,18, 19,21
X	<p>US 6 329 357 B1 (OKAMURA WILLIAM H ET AL) 11 December 2001 (2001-12-11)</p> <p>column 1, line 25 - line 49 column 29, line 12 - line 20 column 36, line 1 - line 18 claims 1,2</p> <p>-----</p>	1,6,7,9, 10,14, 15,17, 18,22,23
X	<p>US 2002/128241 A1 (HAYES COLLEEN E ET AL) 12 September 2002 (2002-09-12)</p> <p>page 1, paragraph 1 page 2, paragraphs 14,24 page 3, paragraphs 26,29 page 4, paragraphs 36,39 page 7, paragraph 67</p> <p>-----</p>	1-5, 10-13
X	<p>WO 98/51663 A (HOFFMANN LA ROCHE ; WOMEN & INFANT S HOSPITAL (US)) 19 November 1998 (1998-11-19)</p> <p>page 3, line 4 - line 23 page 13, line 16 - line 30 page 17, line 6 - line 12 page 18, line 11 - line 15 page 19, line 1 - line 6 page 19, line 29 - page 20, line 9 page 32, line 22 - line 29 claims 1,14,15,23,24</p> <p>-----</p>	1,4-8, 10, 12-16, 18-23
X	<p>EP 1 179 346 A (DOI TOSHIO) 13 February 2002 (2002-02-13)</p> <p>column 1, paragraph 1 column 3, paragraph 27 column 4, paragraphs 31,32 column 6, paragraph 43 claims 1-3</p> <p>-----</p>	1,4,10, 12,18-20

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2004/024517

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>US 2002/045606 A1 (REDDY SATYANARAYANA G ET AL) 18 April 2002 (2002-04-18)</p> <p>page 1, paragraph 6 - page 2, paragraph 14 page 3, paragraphs 18,29,30 page 4, paragraph 39 page 11, paragraphs 100,106 page 12, paragraphs 111,116,117 page 16, paragraph 150 claims 1,49,50</p>	<p>1,4-8, 10, 12-16, 18-23</p>
X	<p>WO 03/050067 A (BERNARDON JEAN-MICHEL ; BIADATTI THIBAUD (FR); GALDERMA RES & DEV (FR)) 19 June 2003 (2003-06-19)</p> <p>page 1, line 3 - line 4 page 2, line 10 - line 25 page 7, line 16 - page 9, line 34</p>	<p>1,4,5, 10,12, 13,18-21</p>
X	<p>PACKARD M J: "VARIATION DURING DEVELOPMENT IN THE RESPONSE OF CHICKEN EMBRYOS TO CALCITRIOL ADMINISTERED VIA SLOW-RELEASE PELLETS" GENERAL AND COMPARATIVE ENDOCRINOLOGY, vol. 85, no. 1, 1992, pages 17-25, XP008039634 ISSN: 0016-6480 abstract page 18, column 1, paragraph 3</p>	<p>1,2,6, 9-11,17</p>
P,X	<p>WO 2004/028515 A (CHOI YOUNG-KWEON) 8 April 2004 (2004-04-08)</p> <p>page 6, line 15 - page 7, line 17 examples 1,8 page 20, lines 19-21 claims 1,2,10</p>	<p>1-4, 10-12, 18-20</p>
P,X	<p>WO 2004/016273 A (MATHES ANGELO ; MARX STEVEN E (US); ABBOTT LAB (US); MELNICK JOEL Z (U) 26 February 2004 (2004-02-26)</p> <p>page 2, line 36 - page 3, line 3 page 6, line 2 - line 16 claims 1-7,11,13,14,16,17</p>	<p>1-23</p>
E	<p>WO 2004/080467 A (BONE CARE INT INC ; STRUGNELL STEPHEN A (US); KNUTSON JOYCE C (US); MA) 23 September 2004 (2004-09-23)</p> <p>page 1, line 9 - line 11 page 5, line 13 - line 20 page 7, line 6 - page 8, line 19 page 9, line 24 - line 27 page 11, line 21 - page 16, line 9 page 18, line 18 - line 29 claims 1,2,4,7</p>	<p>1,2, 5-11, 13-19, 21-23</p>

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2004/024517

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 18-23 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:

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 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.:

1-23 (all partially)

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ 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: 1-23 (all partially)

A sustained release pharmaceutical composition or a pharmaceutical composition for preventing, treating and delaying the progression of kidney disease comprising a therapeutically effective amount of vitamin D receptor activator or vitamin D analog without an ACE inhibitor, an AT(II) receptor (I) blocker or an aldosterone blocker. A method for preventing, treating and delaying the progression of kidney disease in a mammal comprising the step of administering to said mammal such a composition.

2. claims: 1-23 (all partially)

A sustained release pharmaceutical composition or a pharmaceutical composition for preventing, treating and delaying the progression of kidney disease comprising a therapeutically effective amount of vitamin D receptor activator or vitamin D analog and a therapeutically effective amount of at least one member of the group consisting of an ACE inhibitor, an AT(II) receptor (I) blocker or an aldosterone blocker. A method for preventing, treating and delaying the progression of kidney disease in a mammal comprising the step of administering to said mammal such a composition.

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US2004/024517

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