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(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, 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.

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(54) Title: IMPROVED TREATMENTS OF RHEUMATIC AND ARTHRITIC DISEASES COMPRISING COMBINATIONS OF A 5-LIPOXYGENASE INHIBITOR

(57) Abstract: Combination treatments, wherein a 5-LOX inhibitor are administered together with a bone or cartilage beneficial compound in order to obtain a therapeutically beneficial effect in the treatment and/or prophylaxis of osteoarthritis, rheumatoid arthritis, osteoporosis or pain, and pharmaceutical compositions comprising a combination of a 5-LOX inhibitor and a bone and cartilage beneficial compound.



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INTERNATIONAL SEARCH REPORT

International Application No

CT/DK2005/000403

A. CLASSIFICATION OF SUBJECT MATTER

A61P29/00 A61P29/02 A61K31/65 A61K33/24 A61K31/663
A61K31/737 A61K31/519 A61K45/06 A61K31/7008 A61K31/573

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

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, EMBASE, SCISEARCH, CHEM ABS Data, MEDLINE, BIOSIS, CANCERLIT, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	WO 03/020267 A (MERCKLE GMBH; ASCENTIA PHARMA INC; PELLETIER, JEAN-PIERRE; MARTEL-PELL) 13 March 2003 (2003-03-13) page 2; claims 1-8,11,12 pages 15-16 page 11, lines 33,34 ----- -/--	1-4, 10, 16-26, 28-31 1-3, 9, 10, 25, 26, 28-31



Further documents are listed in the continuation of box C.



Patent family members are listed in 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.

* & * document member of the same patent family

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02/12/2005

Name and mailing address of the ISA

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INTERNATIONAL SEARCH REPORT

International Application No

CT/DK2005/000403

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 97/29776 A (G.D. SEARLE & CO; GREGORY, SUSAN, A; ISAKSON, PETER, C; ANDERSON, GARY) 21 August 1997 (1997-08-21)	1,2,13, 16,17, 20,22, 23,25, 26,28, 29,31
Y	page 10, lines 19-30 page 11, lines 19-23 pages 13-14	2,30
Y	-----	2,30
X	WO 03/066048 A (F. HOFFMANN-LA ROCHE AG; THE GOVERNMENT OF THE UNITED STATES; OREGON H) 14 August 2003 (2003-08-14)	1,3,4, 10,13, 14, 16-26, 28,29,31
Y	page 10, lines 4-10; claims 1,2,10,12 pages 1-2; figures 8,9 page 3, lines 14,15 pages 11-12 page 3, line 34 - page 4, line 9 page 13, lines 4-20 page 22, lines 4-12	2,30
Y	-----	2,30
X	EP 0 440 809 A (TORAY INDUSTRIES, INC) 14 August 1991 (1991-08-14)	1,3,11, 16,17, 25,26, 28,31
	page 2, lines 21-36; example 15 page 4, lines 52-55; claims 7,8	
X	WO 03/082188 A (KOCHINKE, FRANK) 9 October 2003 (2003-10-09)	1,3,4, 10,13, 14,16, 17,25, 26,28, 29,31
	page 46; claims 1,12,16	
A	----- VANDERHOEK J Y ET AL: "Endogenous hydroxyeicosatetraenoic acids stimulate the human polymorphonuclear leukocyte 15-lipoxygenase pathway" JOURNAL OF BIOLOGICAL CHEMISTRY 1985 UNITED STATES, vol. 260, no. 29, 1985, pages 15482-15487, XP008051490 page 15482	1-4,10, 16-26, 28-31
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INTERNATIONAL SEARCH REPORT

International Application No

CT/DK2005/000403

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	BRADY H R ET AL: "Lipoxins: Putative braking signals in best defense, inflammation and hypersensitivity" CURRENT OPINION IN NEPHROLOGY AND HYPERTENSION 1996 UNITED STATES, vol. 5, no. 1, 1996, pages 20-27, XP008051486 ISSN: 1062-4821 page 20	1-4,10, 16-26, 28-31
A	CHARLIER C ET AL: "Dual inhibition of cyclooxygenase-2 (COX-2) and 5-lipoxygenase (5-LOX) as a new strategy to provide safer non-steroidal anti-inflammatory drugs" EUROPEAN JOURNAL OF MEDICINAL CHEMISTRY, EDITIONS SCIENTIFIQUE ELSEVIER, PARIS, FR, vol. 38, no. 7-8, July 2003 (2003-07), pages 645-659, XP004448316 ISSN: 0223-5234 cited in the application the whole document	1-4,10, 11,13, 14, 16-26, 28-31
A	EP 1 400 243 A (TANABE SEIYAKU CO., LTD) 24 March 2004 (2004-03-24) paragraph '0039!; claim 5	1,2,25, 26,28,31
A	WO 02/26239 A (TEMPLE UNIVERSITY OF THE COMMONWEALTH SYSTEM OF HIGHER EDUCATION) 4 April 2002 (2002-04-04) page 3, paragraph 1; claims 1,3,7,16 page 5, line 27	1,3,9, 25,26, 28,31

INTERNATIONAL SEARCH REPORT

International application No.
PCT/DK2005/000403

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 25, 26, 28-31 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.:

Partly 1-4, 8-11, 13, 14, 16-26, 28-31
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.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: Partly 1-4, 10, 11, 13, 14, 16-26, 28-31

Combinations of a 5-LOX inhibitor with bisphosphonates, or single compounds thereof, and their use in treatments of osteoarthritis, rheumatoid arthritis or osteoporosis.

2. claims: Partly 1-3, 5, 6, 10-14, 16-26, 28-31

Combinations of a 5-LOX inhibitor with strontium containing compounds, or single compounds thereof (including strontium licofelone salt), and their use in treatments of osteoarthritis, rheumatoid arthritis or osteoporosis.

3. claims: Partly 1-3, 8-11, 13, 14, 16-26, 28-31

Combinations of a 5-LOX inhibitor with glucosamine (including glucosamine sulphate), or single compounds thereof, and their use in treatments of osteoarthritis, rheumatoid arthritis or osteoporosis.

4. claims: Partly 1-3, 8, 10, 11, 13, 14, 16-26, 28-31

Combinations of a 5-LOX inhibitor with DMARDs, including chondroitin sulphate, or single compounds thereof, and their use in treatments of osteoarthritis, rheumatoid arthritis or osteoporosis.

5. claims: Partly 1-3, 7, 10, 11, 13, 14, 16-26, 28-31

Combinations of a 5-LOX inhibitor with SERMs, or single compounds thereof, and their use in treatments of osteoarthritis, rheumatoid arthritis or osteoporosis.

6. claims: Partly 1, 2, 8, 10, 11, 13, 14, 16-26, 28-31

Combinations of a 5-LOX inhibitor with HRT, or single compounds thereof, and their use in treatments of osteoarthritis, rheumatoid arthritis or osteoporosis.

7. claims: Partly 1, 2, 8, 10, 11, 13, 14, 16-26, 28-31

Combinations of a 5-LOX inhibitor with estriol or other physiologically active estrogen metabolites, or single compounds thereof, and their use in treatments of osteoarthritis, rheumatoid arthritis or osteoporosis.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

8. claims: Partly 1, 2, 8, 10, 11, 13, 14, 16-26, 28-31

Combinations of a 5-LOX inhibitor with calcitonin, or single compounds thereof, and their use in treatments of osteoarthritis, rheumatoid arthritis or osteoporosis.

9. claims: Partly 1, 2, 8, 10, 11, 13, 14, 16-26, 28-31

Combinations of a 5-LOX inhibitor with dihydro-tachysterol, or single compounds thereof, and their use in treatments of osteoarthritis, rheumatoid arthritis or osteoporosis.

10. claims: Partly 1, 2, 8, 10, 11, 13, 14, 16-26, 28-31

Combinations of a 5-LOX inhibitor with vitamin D compounds and alphacalcidol, or single compounds thereof, and their use in treatments of osteoarthritis, rheumatoid arthritis or osteoporosis.

11. claims: Partly 1, 2, 8, 10, 11, 13, 14, 16-26, 28-31

Combinations of a 5-LOX inhibitor with PTH (-fragments), or single compounds thereof, and their use in treatments of osteoarthritis, rheumatoid arthritis or osteoporosis.

12. claims: Partly 1, 2, 8, 10, 11, 13, 14, 16-26, 28-31

Combinations of a 5-LOX inhibitor with antagonists / inhibitors of RANK-ligand or osteoprotegrin, or single compounds thereof, and their use in treatments of osteoarthritis, rheumatoid arthritis or osteoporosis.

13. claims: Partly 1, 2, 8, 10, 13, 14, 16-26, 28-31

Combinations of a 5-LOX inhibitor with IL-1 antagonists, N-iminoethyl-L-lysine or 3,4-dialkanoyl- oxybenzylidene dialkanoates, or single compounds thereof, and their use in treatments of osteoarthritis, rheumatoid arthritis or osteoporosis.

14. claims: Partly 1, 2, 8, 10, 11, 13, 14, 16-26, 28-31

Combinations of a 5-LOX inhibitor with TNF-alpha antagonists, or single compounds thereof, and their use in treatments of osteoarthritis, rheumatoid arthritis or osteoporosis.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

15. claims: Partly 1, 2, 8, 10, 11, 13, 14, 16-26, 28-31

Combinations of a 5-LOX inhibitor with GLP-2 (-fragments), or single compounds thereof, and their use in treatments of osteoarthritis, rheumatoid arthritis or osteoporosis.

16. claims: Partly 1, 2, 8, 10, 11, 13, 14, 16-26, 28-31

Combinations of a 5-LOX inhibitor with CLC-7 inhibitors / antagonists, or single compounds thereof, and their use in treatments of osteoarthritis, rheumatoid arthritis or osteoporosis.

17. claims: Partly 1, 2, 8, 10, 11, 13, 14, 16-26, 28-31

Combinations of a 5-LOX inhibitor with inhibitors of cathepsin K, or single compounds thereof, and their use in treatments of osteoarthritis, rheumatoid arthritis or osteoporosis.

18. claims: Partly 1, 2, 8, 10, 11, 13, 14, 16-26, 28-31

Combinations of a 5-LOX inhibitor with SARMs or testosterone, or single compounds thereof, and their use in treatments of osteoarthritis, rheumatoid arthritis or osteoporosis.

19. claims: Partly 1, 2, 8, 10, 11, 13, 14, 16-26, 28-31

Combinations of a 5-LOX inhibitor with N,N-dimethyl-1,1-(4-chlorophenyl) cyclobutyl-3-methylbutylamine HCl, or single compounds thereof, and their use in treatments of osteoarthritis, rheumatoid arthritis or osteoporosis.

20. claims: Partly 1, 2, 8, 10, 11, 13, 14, 16-26, 28-31

Combinations of a 5-LOX inhibitor with polysulphated cyclodextrins or aggrecanase inhibitors, or single compounds thereof, and their use in treatments of osteoarthritis, rheumatoid arthritis or osteoporosis.

21. claims: Partly 1, 2, 8, 10, 11, 13, 14, 16-26, 28-31

Combinations of a 5-LOX inhibitor with selective MMP-13 inhibitors, or single compounds thereof, and their use in treatments of osteoarthritis, rheumatoid arthritis or osteoporosis.

22. claims: Partly 1, 2, 8, 10, 11, 13, 14, 16-26, 28-31

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Combinations of a 5-LOX inhibitor with 2,3,3a,4,5,6,7,7a-octahydroindol-2-carboxylic acids, or single compounds thereof, and their use in treatments of osteoarthritis, rheumatoid arthritis or osteoporosis.

23. claims: Partly 1, 2, 8, 10, 11, 13, 14, 16-26, 28-31

Combinations of a 5-LOX inhibitor with (6-(5-carboxymethyl-hexyloyl)-2,2-dimethyl-hexanoic acid, or single compounds thereof, and their use in treatments of osteoarthritis, rheumatoid arthritis or osteoporosis.

24. claims: partly 1-4, 10, 11, 13, 14, 16-26, 28-31

Combinations of a 5-LOX inhibitor with bisphosphonates, or single compounds thereof, and their use in treatments of pain.

25. claims: partly 1-3, 5, 6, 10-14, 16-26, 28-31

Combinations of a 5-LOX inhibitor with strontium containing compounds, or single compounds thereof (including strontium licofelone salt), and their use in treatments of pain.

26. claims: partly 1-3, 8-11, 13, 14, 16-26, 28-31

Combinations of a 5-LOX inhibitor with glucosamine (including glucosamine sulphate), or single compounds thereof, and their use in treatments of pain.

27. claims: partly 1-3, 8, 10, 11, 13, 14, 16-26, 28-31

Combinations of a 5-LOX inhibitor with DMARDs, including chondroitin sulphate, or single compounds thereof, and their use in treatments of pain.

28. claims: partly 1-3, 7, 10, 11, 13, 14, 16-26, 28-31

Combinations of a 5-LOX inhibitor with SERMs, or single compounds thereof, and their use in treatments of pain.

29. claims: partly 1, 2, 8, 10, 11, 13, 14, 16-26, 28-31

Combinations of a 5-LOX inhibitor with HRT, or single compounds thereof, and their use in treatments of pain.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

30. claims: partly 1, 2, 8, 10, 11, 13, 14, 16-26, 28-31

Combinations of a 5-LOX inhibitor with estriol or other physiologically active estrogen metabolites, or single compounds thereof, and their use in treatments of pain.

31. claims: partly 1, 2, 8, 10, 11, 13, 14, 16-26, 28-31

Combinations of a 5-LOX inhibitor with calcitonin, or single compounds thereof, and their use in treatments of pain.

32. claims: partly 1, 2, 8, 10, 11, 13, 14, 16-26, 28-31

Combinations of a 5-LOX inhibitor with dihydro-tachysterol, or single compounds thereof, and their use in treatments of pain.

33. claims: partly 1, 2, 8, 10, 11, 13, 14, 16-26, 28-31

Combinations of a 5-LOX inhibitor with vitamin D compounds and alphacalcidol, or single compounds thereof, and their use in treatments of pain.

34. claims: partly 1, 2, 8, 10, 11, 13, 14, 16-26, 28-31

Combinations of a 5-LOX inhibitor with PTH (-fragments), or single compounds thereof, and their use in treatments of pain.

35. claims: partly 1, 2, 8, 10, 11, 13, 14, 16-26, 28-31

Combinations of a 5-LOX inhibitor with antagonists / inhibitors of RANK-ligand or osteoprotegerin, or single compounds thereof, and their use in treatments of pain.

36. claims: partly 1, 2, 8, 10, 11, 13, 14, 16-26, 28-31

Combinations of a 5-LOX inhibitor with IL-1 antagonists, N-iminoethyl-L-lysine or 3,4-dialkanoyl- oxybenzylidene dialkanoates, or single compounds thereof, and their use in treatments of pain.

37. claims: partly 1, 2, 8, 10, 11, 13, 14, 16-26, 28-31

Combinations of a 5-LOX inhibitor with TNF-alpha antagonists, or single compounds thereof, and their use in treatments of pain.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

38. claims: partly 1, 2, 8, 10, 11, 13, 14, 16-26, 28-31

Combinations of a 5-LOX inhibitor with GLP-2 (-fragments), or single compounds thereof, and their use in treatments of pain.

39. claims: partly 1, 2, 8, 10, 11, 13, 14, 16-26, 28-31

Combinations of a 5-LOX inhibitor with CLC-7 inhibitors / antagonists, or single compounds thereof, and their use in treatments of pain.

40. claims: partly 1, 2, 8, 10, 11, 13, 14, 16-26, 28-31

Combinations of a 5-LOX inhibitor with inhibitors of cathepsin K, or single compounds thereof, and their use in treatments of pain.

41. claims: partly 1, 2, 8, 10, 11, 13, 14, 16-26, 28-31

Combinations of a 5-LOX inhibitor with SARMs or testosterone, or single compounds thereof, and their use in treatments of pain.

42. claims: partly 1, 2, 8, 10, 11, 13, 14, 16-26, 28-31

Combinations of a 5-LOX inhibitor with N,N-dimethyl-1,1-(4-chlorophenyl) cyclobutyl-3-methylbutylamine HCl, or single compounds thereof, and their use in treatments of pain.

43. claims: partly 1, 2, 8, 10, 11, 13, 14, 16-26, 28-31

Combinations of a 5-LOX inhibitor with polysulphated cyclodextrins or aggrecanase inhibitors, or single compounds thereof, and their use in treatments of pain.

44. claims: partly 1, 2, 8, 10, 11, 13, 14, 16-26, 28-31

Combinations of a 5-LOX inhibitor with selective MMP-13 inhibitors, or single compounds thereof, and their use in treatments of pain.

45. claims: partly 1, 2, 8, 10, 11, 13, 14, 16-26, 28-31

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Combinations of a 5-LOX inhibitor with
2,3,3a,4,5,6,7,7a-octahydroindol-2-carboxylic acids, or
single compounds thereof, and their use in treatments of
pain.

46. claims: partly 1, 2, 8, 10, 11, 13, 14, 16-26, 28-31

Combinations of a 5-LOX inhibitor with
(6-(5-carboxymethyl-hexyloyl)-2,2-dimethyl-hexanoic acid, or
single compounds thereof, and their use in treatments of
pain.

47. claims: partly 15, 27-31

Combinations of a 5-LOX inhibitor with a corticosteroid, or
single compounds thereof, and their use in treatments of
osteoarthritis, rheumatoid arthritis or osteoporosis.

48. claims: partly 15, 27-31

Combinations of a 5-LOX inhibitor with a corticosteroid, or
single compounds thereof, and their use in treatments of
pain.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/DK2005/000403

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
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