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(54) Title: FIXED DOSE DRUG COMBINATION FORMULATIONS

(57) Abstract: Pharmaceutical formulations comprising multiple drugs, for treating or preventing cardiovascular disease. Embodi- ments are capsules containing individual drugs, or combinations of drugs, in the form of small tablets.



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**A. CLASSIFICATION OF SUBJECT MATTER***A61K 9/20(2006.01)i, A61K 9/48(2006.01)i, A61K 31/19(2006.01)i, A61K 31/16(2006.01)i*

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)

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Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Korean utility models and applications for utility models

Japanese utility models and applications for utility models

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

eKOMPASS(KIPO internal), GOOGLE, PUBMED

Keywords: fixed dose drug combination formulation, HMG CoA reductase inhibitor, ACE inhibitor, diuretic, hypertension, tablet

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2005-0054731 A1 (FRANCO FOLLI et al.) 10 March 2005 See abstract; paragraphs [0013], [0016], [0020]; claims 1-45.	1-38
X	US 7205295 B2 (WARNER-LAMBERT COMPANY LLC) 17 April 2007 See abstract; column 32, lines 4-13.	1-38
Y	WO 01-15674 A2 (AVENTIS PHARMA DEUTSCHLAND GMBH) 08 March 2001 See abstract; page 12, lines 28, 33; page 13, lines 3-5, 23; page 14, line 19.	1-38
Y	WO 2005-113506 A1 (IRM LLC et al.) 01 December 2005 See abstract; paragraphs [0034], [0035], [0043], [0045], [0047].	1-38

 Further documents are listed in the continuation of Box C. See patent family annex.

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"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

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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2005-0054731 A1	10.03.2005	CA 2538333-A1	24.03.2005
		DE 602004022176 D1	03.09.2009
		EP 1663395 A1	07.06.2006
		EP 1663395 B1	22.07.2009
		ES 2328821 T3	18.11.2009
		WO 2005-025673 A1	24.03.2005
		US 7205295 B2	17.04.2007
WO 01-15674 A2	08.03.2001	AU 2000-76491 A1	26.03.2001
		AU 2005-209687 A1	06.10.2005
		AU 2009-200746 A1	19.03.2009
		CA 2382549-A1	08.03.2001
		CA 2488370-A1	08.03.2001
		CN 1268331 C	09.08.2006
		CN 1268331 C0	09.08.2006
		DE 60022525 D1	13.10.2005
		DE 60022525 T2	14.06.2006
		EP 1216038 A2	26.06.2002
		EP 1216038 B1	07.09.2005
		EP 1611886 A2	04.01.2006
		EP 1611886 A3	04.06.2008
		JP 2003-527325 A	16.09.2003
		JP 2003-527325 T	16.09.2003
		KR 10-2002-0040795 A	30.05.2002
		RU 2005141759 A	10.07.2007
		RU 2276997 C2	27.05.2006
		WO 01-15674 A3	28.03.2002
		WO 01-15674 A3	08.03.2001
WO 2005-113506 A1	01.12.2005	AU 2005-245418 A1	01.12.2005
		AU 2005-245418 B2	27.11.2008
		BR P10510024A	25.09.2007
		CA 2564365-A1	01.12.2005
		CN 1980894 A	13.06.2007
		CN 1980894 C0	13.06.2007
		EP 1756062 A1	28.02.2007
		EP 1756062 A4	02.01.2008
		JP 2007-537289 A	20.12.2007
		JP 2007-537289 T	20.12.2007
		KR 20070026503A	08.03.2007
		MX PA06013195A	14.02.2007
		US 2007-259890 A1	08.11.2007
		US 7745445 B2	29.06.2010