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(54) **Title:** LIQUID AND FREEZE DRIED FORMULATIONS

(57) **Abstract:** The present invention relates to stable parenteral formulations comprising a new class of compounds, which is a non proteinic compound, a method for preparing such formulations as well as the use of certain compounds for stabilizing these formulations.



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# INTERNATIONAL SEARCH REPORT

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**A. CLASSIFICATION OF SUBJECT MATTER**  
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**B. FIELDS SEARCHED**

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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, BIOSIS, EMBASE

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 99/44604 A (SHIONOGI & CO [JP]; CONFER WILLIAM LESTER [US]; TAI HIDEAKI [JP]) 10 September 1999 (1999-09-10) claims 1-27	1-13
X	EP 1 762 249 A (ALTANA PHARMA AG [DE]) 14 March 2007 (2007-03-14) examples 1-4 claims 1-21	1-13
X	WO 2005/102274 A (PFIZER PROD INC [US]; PIKAL MICHAEL J [US]; REDDY RENUKA DEVI [US]; SH) 3 November 2005 (2005-11-03) example 1	1-13
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See patent family annex.

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## INTERNATIONAL SEARCH REPORT

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PCT/IB2009/005441

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 443 471 A (YOSHITOMI PHARMACEUTICAL [JP]; YAMASA SHOYU KK [JP]) 28 August 1991 (1991-08-28) example 3	1-13
X	WO 02/41919 A (BYK GULDEN LOMBERG CHEM FAB [DE]; DIETRICH RANGO [DE]; LINDER RUDOLF [DE]) 30 May 2002 (2002-05-30) examples 1-4	1-13
X	GB 2 248 550 A (SANDOZ LTD [CH]) 15 April 1992 (1992-04-15) examples 1-14	1-13
X	WO 03/097101 A (NOVUSPHARMA SPA [IT]; BERNAREGGI ALBERTO [IT]; LIVI VALERIA [IT]) 27 November 2003 (2003-11-27) claims 1-11	1-13
Y	SAVEANU ALEXANDRU ET AL: "SOMATOSTATIN AND DOPAMINE-SOMATOSTATIN MULTIPLE LIGANDS DIRECTED TOWARDS SOMATOSTATIN AND DOPAMINE RECEPTORS IN PITUITARY ADENOMAS" NEUROENDOCRINOLOGY, S.KARGER, BASEL, CH, vol. 83, no. 3-4, 1 January 2006 (2006-01-01), pages 258-263, XP009085931 ISSN: 0028-3835 the whole document	11-13
Y	ANDERSEN M: "The role of lanreotide Autogel(R) in the treatment of acromegaly" EXPERT REVIEW OF ENDOCRINOLOGY AND METABOLISM 200707 GB, vol. 2, no. 4, July 2007 (2007-07), pages 433-441, XP001538509 ISSN: 1744-6651 the whole document	11-13
Y	JAQUET P ET AL: "BIM-23A760, a chimeric molecule directed towards somatostatin and dopamine receptors, vs universal somatostatin receptors ligands in GH-secreting pituitary adenomas partial responders to octreotide." JOURNAL OF ENDOCRINOLOGICAL INVESTIGATION 2005, vol. 28, no. 11 Suppl International, 2005, pages 21-27, XP009103539 ISSN: 0391-4097 the whole document	11-13

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No  
PCT/IB2009/005441

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9944604	A	10-09-1999	AT 310513 T 15-12-2005
			AU 757002 B2 30-01-2003
			AU 2799899 A 20-09-1999
			BR 9908479 A 05-12-2000
			CA 2322796 A1 10-09-1999
			CN 1299277 A 13-06-2001
			DE 69928500 D1 29-12-2005
			DE 69928500 T2 03-08-2006
			EP 1058547 A1 13-12-2000
			ES 2253877 T3 01-06-2006
			HU 0102812 A2 28-12-2001
			ID 27487 A 12-04-2001
			JP 2002505282 T 19-02-2002
			JP 2006096761 A 13-04-2006
			NO 20004306 A 10-10-2000
			NZ 506578 A 26-09-2003
			PL 342822 A1 02-07-2001
			TR 200002543 T2 21-11-2000
			TW 570795 B 11-01-2004
			EP 1762249
AU 1604202 A 03-06-2002			
AU 2002216042 B2 03-08-2006			
BG 107828 A 30-07-2004			
BR 0115483 A 21-10-2003			
CA 2428870 A1 30-05-2002			
CA 2541946 A1 30-05-2002			
CN 1476335 A 18-02-2004			
CZ 20031416 A3 17-09-2003			
DE 60132108 T2 11-12-2008			
DK 1339430 T3 13-05-2008			
EC SP034613 A 29-08-2003			
EE 200300182 A 16-06-2003			
WO 0241919 A1 30-05-2002			
EP 1339430 A1 03-09-2003			
ES 2298295 T3 16-05-2008			
HK 1060848 A1 24-11-2006			
HR 20030410 A2 30-04-2005			
HU 0303278 A2 28-01-2004			
IL 155601 A 29-12-2008			
IS 6820 A 19-05-2003			
JP 2004513970 T 13-05-2004			
KR 20080003010 A 04-01-2008			
MX PA03004548 A 10-09-2003			
NO 20032303 A 21-05-2003			
NZ 525911 A 26-11-2004			
PL 361118 A1 20-09-2004			
PT 1339430 E 27-03-2008			
SI 1339430 T1 30-06-2008			
SK 6062003 A3 07-10-2003			
TW 284041 B 21-07-2007			
UA 80961 C2 26-11-2007			
US 2009093522 A1 09-04-2009			
US 2003003058 A1 02-01-2003			
US 2004220228 A1 04-11-2004			
YU 37703 A 25-05-2006			
ZA 200303593 A 23-04-2004			

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No  
PCT/IB2009/005441

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2005102274 A	03-11-2005	AT 374624 T	15-10-2007
		BR PI0509992 A	16-10-2007
		CA 2563665 A1	03-11-2005
		DE 602005002742 T2	24-01-2008
		EP 1740214 A2	10-01-2007
		ES 2292122 T3	01-03-2008
		JP 2007533724 T	22-11-2007
		US 2008096858 A1	24-04-2008
EP 0443471 A	28-08-1991	AT 118012 T	15-02-1995
		CA 2036507 A1	20-08-1991
		DE 69107098 D1	16-03-1995
		DK 0443471 T3	26-06-1995
		ES 2067780 T3	01-04-1995
		JP 1888153 C	07-12-1994
		JP 3240794 A	28-10-1991
		JP 6015557 B	02-03-1994
		US 5183882 A	02-02-1993
WO 0241919 A	30-05-2002	AT 381946 T	15-01-2008
		AU 1604202 A	03-06-2002
		AU 2002216042 B2	03-08-2006
		BG 107828 A	30-07-2004
		BR 0115483 A	21-10-2003
		CA 2428870 A1	30-05-2002
		CA 2541946 A1	30-05-2002
		CN 1476335 A	18-02-2004
		CZ 20031416 A3	17-09-2003
		DE 60132108 T2	11-12-2008
		DK 1339430 T3	13-05-2008
		EC SP034613 A	29-08-2003
		EE 200300182 A	16-06-2003
		EP 1339430 A1	03-09-2003
		EP 1762249 A2	14-03-2007
		ES 2298295 T3	16-05-2008
		HK 1060848 A1	24-11-2006
		HR 20030410 A2	30-04-2005
		HU 0303278 A2	28-01-2004
		IL 155601 A	29-12-2008
		IS 6820 A	19-05-2003
		JP 2004513970 T	13-05-2004
		KR 20080003010 A	04-01-2008
		MX PA03004548 A	10-09-2003
		NO 20032303 A	21-05-2003
		NZ 525911 A	26-11-2004
		PL 361118 A1	20-09-2004
		PT 1339430 E	27-03-2008
		SI 1339430 T1	30-06-2008
		SK 6062003 A3	07-10-2003
TW 284041 B	21-07-2007		
UA 80961 C2	26-11-2007		
US 2009093522 A1	09-04-2009		
US 2003003058 A1	02-01-2003		
US 2004220228 A1	04-11-2004		
YU 37703 A	25-05-2006		
ZA 200303593 A	23-04-2004		

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No PCT/IB2009/005441
---------------------------------------------------

Patent document cited in search report	A	Publication date	Patent family member(s)	Publication date
GB 2248550	A	15-04-1992	AU 8464791 A	26-03-1992
GB 2248550	A		CA 2051721 A1	21-03-1992
			CH 683749 A5	13-05-1994
			CS 9102854 A3	15-04-1992
			DE 4131232 A1	26-03-1992
			EP 0490806 A2	17-06-1992
			FI 914398 A	21-03-1992
			FR 2666987 A1	27-03-1992
			FR 2681326 A1	19-03-1993
			IE 913296 A1	25-02-1992
			IT 1255258 B	20-10-1995
			JP 4247034 A	03-09-1992
			LU 88006 A1	15-04-1993
			MX 9101175 A1	04-05-1992
			PT 99007 A	31-08-1992
			ZA 9107528 A	22-03-1993
WO 03097101	A	27-11-2003	AT 381944 T	15-01-2008
			AU 2003240613 A1	02-12-2003
			CA 2486001 A1	27-11-2003
			DE 60318310 T2	11-12-2008
			EP 1503797 A1	09-02-2005
			ES 2298521 T3	16-05-2008
			IT MI20021040 A1	17-11-2003
			JP 2005530792 T	13-10-2005
			MX PA04011348 A	15-08-2005
			US 2006199831 A1	07-09-2006