(19) World Intellectual Property **Organization**

International Bureau





(43) International Publication Date 3 March 2005 (03.03.2005)

PCT

(10) International Publication Number WO 2005/018530 A3

(51) International Patent Classification⁷: A61K 9/12, 31/196, 31/167, 7/48, 31/496

(21) International Application Number:

PCT/IB2004/002965

(22) International Filing Date: 20 August 2004 (20.08.2004)

(25) Filing Language:

(26) Publication Language: English

(30) Priority Data:

60/497,648 25 August 2003 (25.08.2003)

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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, 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.

(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).

Published:

- with international search report
- (88) Date of publication of the international search report: 20 October 2005

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: PENETRATING PHARMACEUTICAL FOAM

(57) Abstract: The invention relates to an alcohol-free cosmetic or pharmaceutical foam carrier comprising water, a hydrophobic solvent, a surface-active agent and a gelling agent. The foam carrier further comprises active agents and excipients with therapeutic properties having enhanced skin penetration.

Inter Phal Application No PCT/IB2004/002965

A. CLASSIFICATION OF SUBJECT MATTER I PC 7 A61K9/12 A61F A61K7/48 A61K31/196 A61K31/167 A61K31/496 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, WPI Data, PAJ C. DOCUMENTS CONSIDERED TO BE RELEVANT Citation of document, with indication, where appropriate, of the relevant passages Relevant to claim No. Χ PATENT ABSTRACTS OF JAPAN 1,3-5,9, vol. 2002, no. 05, 3 May 2002 (2002-05-03) 13-56, & JP 2002 012513 A (KANEBO LTD), 58, 15 January 2002 (2002-01-15) 61-63,65, 68-71. 79,80 abstract example 4 -/--Further documents are listed in the continuation of box C. Х Patent family members are listed in annex. ° Special categories of cited documents: "T" later document published after the international filing date or priority date and not in conflict with the application but "A" document defining the general state of the art which is not considered to be of particular relevance cited to understand the principle or theory underlying the "E" earlier document but published on or after the international "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 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) "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 act of "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 "&" document member of the same patent family Date of the actual completion of the international search Date of mailing of the international search report 18 JUL 2005 3 May 2005 Name and mailing address of the ISA Authorized officer European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016 Marttin, E

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C.(Continua	ation) DOCUMENTS CONSIDERED TO BE RELEVANT	
Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Х	US 4 145 411 A (MENDE ET AL) 20 March 1979 (1979-03-20) cited in the application	63
A	column 1, line 63 - last line	1,3-5,9, 13-56, 58, 60-62, 65, 67-70, 74,78-80
	column 3, line 8 - line 18; claim 1; example 1	
Α	US 5 972 310 A (SACHETTO ET AL) 26 October 1999 (1999-10-26)	1,3-5,9, 13-56, 58, 60-63, 65, 67-70, 74,78-80
	column 2, line 8 - line 23 column 3, line 22 - column 5, line 33; examples 1,2; table II	
Α	WO 02/41847 A (WELLA AKTIENGESELLSCHAFT; BROCKS, WERNER; EBERHARDT, HEIKO; KALBFLEISC) 30 May 2002 (2002-05-30)	1,3-5,9, 13-56, 58, 60-63, 65, 67-70, 74,78-80
	example 2	74,76-60

formation on patent family members

Intermonal Application No
PCT/IB2004/002965

Patent document cited in search report		Publication date		Patent family member(s)		Publication date
JP 2002012513	Α	15-01-2002	NONE			
US 4145411	Α	20-03-1979	NONE			
US 5972310	Α	26-10-1999	AT AU	207737 701373		15-11-2001 28-01-1999
			AU	2988095		22-02-1996
			BR	9508788	Α	25-11-1997
			CA	2195079	A1	08-02-1996
			CN	1158565	Α	03-09-1997
			CZ	9700171	A3	16-07-1997
			DE	69523602	D1	06-12-2001
			DE	69523602		20-06 - 2002
			EP	0774957		28-05-1997
			ES	2166829	T3	01-05-2002
			FI	970240		20-03-1997
			WO	9603115		08-02-1996
			HU	77528		28-05-1998
			JP	11503716		30-03-1999 20-01-1997
			NO NZ	970239 289903		28-10-1998
			PL	318315		09-06-1997
			US	5759520		02-06-1998
WO 0241847	Α	30-05-2002	DE	10058384	A1	06-06-2002
,,, ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,			ĀŪ	1697102		03-06-2002
			WO	0241847	A1	30-05-2002
			EP	1337226		27-08-2003
			JP	2004513958		13-05-2004
			US	2004076651	A1	22-04-2004



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. X	Claims Nos.: because they relate to subject matter not required to be searched by this Authority, namely:				
	Although claims 26-28, 61-63, 65, 67-70, 74, and 78-80 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 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 Inte	rnational 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. X	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.: See annex				
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 (in part), 3-5, 9, 13-56 (in part), 58, 60-63 (in part), 65, 67 (in part), 68-70, 74, 78-80 (in part)

An oil in water foamable emulsion that is stable in its pre-dispensed state comprising: (i) 5-50% by weight of composition of a liquid, non-volatile hydrophobic solvent; (ii) 0.1 to 5% by weight of a composition of a surface-active agent; (iii) 0.1 to 5% by weight of a gelling agent; (iv) urea; and (v) a liquefied gas propellant at a concentration of 3% to 18% by weight of the total composition; wherein the emulsion is alcohol-free; a foam, comprising: (i) 0.1 to 5% by weight of a composition of a surface-active agent; (ii) 0.1 to 5% by weight of a gelling agent; (iii) 10% to 40% urea; and (iv) water wherein the foam is alcohol-free and has a specific gravity of between 0.01 g/mL and 0.1 g/mL; and use of said foamable emulsion or foam in the treatment of a disorder, wounds, burns, cuts and ulcers.

2. claims: 1 (in part), 6-8, 13-56 (in part), 59, 60-63 (in part), 66, 67 (in part), 71-73, 78-80 (in part)

An oil in water foamable emulsion that is stable in its pre-dispensed state comprising: (i) 5-50% by weight of composition of a liquid, non-volatile hydrophobic solvent; (ii) 0.1 to 5% by weight of a composition of a surface-active agent; (iii) 0.1 to 5% by weight of a gelling agent; (iv) a hydroxy acid; and (v) a liquefied gas propellant at a concentration of 3% to 18% by weight of the total composition; wherein the emulsion is alcohol-free; a foam, comprising: (i) 0.1 to 5% by weight of a composition of a surface-active agent; (ii) 0.1 to 5% by weight of a gelling agent; (iii) 10% to 30% hydroxy acid; and (iv) water wherein the foam is alcohol-free and has a specific gravity of between 0.01 g/mL and 0.1 g/mL; and use of said foamable emulsion or foam in the treatment of a disorder, wounds, burns, cuts and ulcers.

3. claims: claims 1 (in part), 2, 14-56 (in part), 57, 60 (in part)-63 (in part), 64, 67 (in part), 78-80 (in part)

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

An oil in water foamable emulsion that is stable in its pre-dispensed state comprising: (i) 5-50% by weight of composition of a liquid, non-volatile hydrophobic solvent; (ii) 0.1 to 5% by weight of a composition of a surface-active agent; (iii) 0.1 to 5% by weight of a gelling agent; (iv) a eutectic mixture of active agents; and (v) a liquefied gas propellant at a concentration of 3% to 18% by weight of the total composition; wherein the emulsion is alcohol-free; a foam, comprising: (i) 0.1 to 5% by weight of a composition of a surface-active agent; (ii) 0.1 to 5% by weight of a gelling agent; (iii) a eutectic mixture of active agents; and (iv) water wherein the foam is alcohol-free and has a specific gravity of between 0.01 g/mL and 0.1 g/mL; and use of said foamable emulsion or foam in the treatment of a disorder, wounds, burns, cuts and ulcers.

4. claims: claims 10-12, 14-56 (in part), 63 (in part), 67 (in part), 75-77, 78-80 (in part)

An oil in water foamable emulsion that is stable in its pre-dispensed state comprising: (i) 5-50% by weight of composition of a liquid, non-volatile hydrophobic solvent: (ii) 0.1 to 5% by weight of a composition of a surface-active agent; (iii) 0.1 to 5% by weight of a gelling agent; (iv) a therapeutic enhancer selected from the group consisting of propylene glycol, butylene glycols, glycerol. pentaerythritol, sorbitol, mannitol, oligosaccharides, dimethyl isosorbide, monooleate of ethoxylated glycerides having 8 to 10 ethylene oxide units, polyethylene glycol 200-600, transcutol, glycofurol and cyclodextrins; (v) a therapeutically effective concentration of at least one active agent; and (vi) a liquefied gas propellant at a concentration of 3% to 18% by weight of the total composition; wherein the emulsion is alcohol-free; and use of said foamable emulsion or foam in the treatment of a disorder, wounds, burns, cuts and ulcers.