(19) World Intellectual Property **Organization**

International Bureau





(43) International Publication Date 28 October 2004 (28.10.2004)

(10) International Publication Number WO 2004/091498 A3

(51) International Patent Classification⁷: A61K 33/00

(21) International Application Number:

PCT/US2004/011056

(22) International Filing Date: 8 April 2004 (08.04.2004)

(25) Filing Language: English

English (26) Publication Language:

(30) Priority Data:

10/412,637 11 April 2003 (11.04.2003)

(71) Applicant (for all designated States except US): ALL NATURAL FMG, INC. [US/US]; 372 Golfview Road, North Palm Beach, FL 33408 (US).

(72) Inventor: FISHMAN, Robert; 1875 N.W. 138th Terrace, Pembroke Pines, FL 33028 (US).

(74) Agent: SLAVIN, Michael, A.; McHale & Slavin, P.A., 2855 PGA Boulevard, Palm Beach Gardens, FL 33410 (US).

(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, 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).

Declarations under Rule 4.17:

- as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii)) for all designations
- as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii)) for all designations

Published:

with international search report

(88) Date of publication of the international search report:

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: ALCOHOL-FREE TRANSDERMAL INSULIN COMPOSITION AND PROCESSES FOR MANUFACTURE AND USE THEREOF

(57) Abstract: The instant invention is directed toward a dermal delivery system composition comprising an aqueous base vehicle including American Emu oil, Isopropyl Palmitate (PROTACHEM IPP), PEG-8 (a polyethylene glycol available under the tradename PROTACHEM 400), methylsulfonylmethane (MSM)and SEPIGEL 305 (a combination including polyacrylamide/C₁₃-C₁₄ Iso-paraffin and LAURETH 7, in combination with a therapeutically effective amount of at least one species of insulin, and to processes for the manufacture and use thereof.



INTERNATIONAL SEARCH REPORT

International application No.

PCT/US04/11056

A. CLASSIFICATION OF SUBJECT MATTER IPC(7) : A61K 33/00 US CL : 435/6; 530/303; 514/3 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) U.S.: 435/6; 530/303; 514/3		
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 practicable, search terms used) west and STN		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category * Citation of document, with indication, where		Relevant to claim No.
X US 6,720,001 A (Chen et al) 13 April 2004 (13.04 15 and 19		1-4
Further documents are listed in the continuation of Box C.	See patent family annex.	1.51
Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance	"T" later document published after the inte date and not in conflict with the applic principle or theory underlying the inve "X" document of particular relevance; the	cation but cited to understand the ention
"E" earlier application or patent published on or after the international filing date	considered novel or cannot be conside when the document is taken alone	
"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 considered to involve an inventive ste combined with one or more other such	when the document is
"O" document referring to an oral disclosure, use, exhibition or other means	being obvious to a person skilled in th	
"P" document published prior to the international filing date but later than the priority date claimed	"&" document member of the same patent	
Date of the actual completion of the international search Date of mailing of the international search report 21 December 2004 (21.12.2004)		
A December 2004 1.12.2001		
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450	Roy Teller Telephone No. 571-272-1600	
Facsimile No. (703)305-3230	<u></u>	

Form PCT/ISA/210 (second sheet) (January 2004)