(19) World Intellectual Property **Organization**

International Bureau





(43) International Publication Date 27 May 2004 (27.05.2004)

(10) International Publication Number WO 2004/043351 A3

(51) International Patent Classification⁷:

A61F 13/00

(21) International Application Number:

PCT/US2003/034549

(22) International Filing Date: 29 October 2003 (29.10.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

10/287,843 5 November 2002 (05.11.2002)

(63) Related by continuation (CON) or continuation-in-part (CIP) to earlier applications:

US 10/287.843 (CON)

Filed on 5 November 2002 (05.11.2002) US 60/236,289 (CIP)

Filed on 4 September 2002 (04.09.2002)

(71) Applicant and

(72) Inventor: HALEY, Jeffrey, T. [US/US]; 4730-91st Avenue Southeast, Mercer Island, WA 98040 (US).

(74) Agents: HALEY, Jeffrey, T. et al.; Graybeal Jackson Haley LLP, Suite 350, 155 - 180th Avenue Northeast, Bellevue, WA 98004 (US).

(81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, 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, 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 (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

- with international search report
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments
- (88) Date of publication of the international search report: 26 August 2004

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: SOLUBLE ORAL PATCH WITH COLLAGEN AND INTERLACED ACTIVE INGREDIENTS

(57) Abstract: An adherent, soluble oral patch for delivering topical medication in the mouth including a hydrophilic polymer that is liquid at human mouth temperatures. Preferably, the hydrophilic polymer gels to a solid at temperatures just below human mouth temperatures, preferably collagen such as animal gelatin. The structure of the oral patch is formed with a porous network that remains solid at human mouth temperatures and slowly dissolves in saliva. In some embodiments, the network is elasto-plastic and in some cases it is hydrophilic. The hydrophilic polymer is located within pores of the network, along with a desired medication. The oral patch is formed by mixing and hydrating the ingredients, bringing them to above an activation temperature below boiling, and cooling them to form a gel. The hot mixture may be poured into molds, including a flat sheet, and the mold may also serve as packaging for delivery. The packaging may comprise a germ barrier moisture passing film which allows the oral patch to dry out or become re-hydrated without growing mold.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/34549

A. CLASSIFICATION OF SUBJECT MATTER IPC(7) : A61F 13/00 US CL : 424/435 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.: 424/435, 449, 488					
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) EAST BRS Search, oral-transdermal-cellulose-steroid-lozenge					
C. DOCUMENTS CONSIDERED TO BE RELEVANT					
Category *	Citation of document, with indication, where appropriate, of the relevant passages			Relevant to claim No.	
Y	US 6,319,510 B1 (YATES) 20 November 2001 (20.11.2001), entire document.			1-45	
Y	US 6,174,873 B1 (WRENN, JR.) 16 January 2001 (16.01.2001), entire document.			1-45	
	i.	——			
	r documents are listed in the continuation of Box C.		See patent family annex.		
Special categories of cited documents: document defining the general state of the art which is not considered to be of particular relevance.		"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		
"E" earlier ap	"E" earlier application or patent published on or after the international filing date			ument of particular relevance; the claimed invention cannot be sidered novel or cannot be considered to involve an inventive step en 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 claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination		
"O" documen	at referring to an oral disclosure, use, exhibition or other means		being obvious to a person skilled in the	e art	
"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 February 2004 (18.02.2004)			3 V JUN 2004		
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 Facsimile No. (703) 305-3230		Mican-Paul Young Turkers Low			

Form PCT/ISA/210 (second sheet) (July 1998)