(19) World Intellectual Property Organization

International Bureau





(10) International Publication Number

WO 2007/075963 A3

(43) International Publication Date 5 July 2007 (05.07.2007)

(51) International Patent Classification: A01N 45/00 (2006.01) A61K 31/56 (2006.01)

(21) International Application Number:

PCT/US2006/048927

(22) International Filing Date:

19 December 2006 (19.12.2006)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

60/752,735	20 December 2005 (20.12.2005)	US
60/752,332	20 December 2005 (20.12.2005)	US
60/752,765	20 December 2005 (20.12.2005)	US
60/773,999	15 February 2006 (15.02.2006)	US
60/773,998	15 February 2006 (15.02.2006)	US
60/820,094	21 July 2006 (21.07.2006)	US
60/820,092	21 July 2006 (21.07.2006)	US
60/820,096	21 July 2006 (21.07.2006)	US

- (71) Applicant (for all designated States except US): TIKA LÄKEMEDEL AB [SE/SE]; Västra-Malarehamnen 9, S-151 85 Södertälje (SE).
- (72) Inventor; and
- (75) Inventor/Applicant (for US only): HILL, Malcolm, R. [US/US]; 12671 High Bluff Drive, Suite 200, San Diego, CA 92130 (US).

- (74) Agent: VARMA, Anita; Ropes & Gray LLP, One International Place, Boston, MA 02110-2624 (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, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, 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, IS, IT, LT, LU, LV, 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
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments
- with information concerning request for restoration of the right of priority in respect of one or more priority claims
- (88) Date of publication of the international search report: 27 November 2008



(54) Title: SYSTEMS AND METHODS FOR THE DELIVERY OF CORTICOSTEROIDS

(57) Abstract: The present invention relates to methods and systems for the delivery of a corticosteroid comprising (1) an inhalable aqueous mixture comprising a corticosteroid and a solubility enhancer and (2) an inhalable nebulizer, wherein the delivery of the aqueous mixture comprising the corticosteroid by the nebulizer results in an enhanced pharmacokinetic profile of the corticosteroid as compared to conventional inhalable therapies and/or increase lung deposition.

INTERNATIONAL SEARCH REPORT

International application No. PCT/US 06/48927

A. CLASSIFICATION OF SUBJECT MATTER IPC(8) - A01N 45/00 (2008.04); A61K 31/56 (2008.04) USPC - 514/169					
According to International Patent Classification (IPC) or to both national classification and IPC					
B. FIELI	OS SEARCHED		·		
Minimum documentation searched (classification system followed by classification symbols) USPC - 514/169 IPC(8)- A01N 45/00 (2008.04); A61K 31/56 (2008.04)					
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) PubWest, USTPO, Google Scholar, Google Patent, Public Pair: coticosteroid, aqeous, solub\$6, solubility, enhanc\$4, solubility enhancer, nebulizer, solvent, adminstrat\$5, concentration, increaes, rise, inhaler, treatment, lung, asthma, brocheoconstriction					
C. DOCUMENTS CONSIDERED TO BE RELEVANT					
Category*	Citation of document, with indication, where ap	Relevant to claim No.			
X Y	US 5,192,528 A (RADHAKRISHMAN et al.) 9 Mar 1993 24-40; col 3, ln 2-40; col 3, ln 42-43; col 6, ln 9-19; col col 3, ln 3; col 7, ln 38-50; col 7, ln 50-65	1-4, 8, 10-13, 17, 21-23, 27, 31-33, 37, 41-44, 46, 51-56, 60, 62-66, 69, 73-75, 79, 83-85, 89, 93-96, 99, 103-104			
			5-7, 9, 14-16, 18-20,24- 26, 28-30,34-36, 38-40, 45, 47-50, 57-59, 61, 67, 68, 70-72, 76-78, 80-82, 86-88, 90-92, 97-98, 100- 102		
Υ	US 2004/0228805 A1 (PIIEPER et al.) 18 Nov. 2004 (1	5, 18, 28, 38, 48,57, 70, 80, 90, 100			
Y	US 5,874,418 A (STELLA et al.) 23 Feb 1999 (23.02.19	6-7, 19, 20, 29, 30, 39, 40, 49, 50, 58, 59, 71, 72, 81, 82, 91, 92, 101, 102			
			9, 61		
Y	US 2005/0065141 A1 (ODINK et al.) 24 Mar 2005 (24.0	14-16, 24-26, 34-36, 45, 47, 67, 68, 76, 77, 78, 86, 87, 88, 97, 98			
Y	European Respiratory Journal 17:14-19 (2001) ?Ultrasi several pulmonary ypertension? (GESSLER et al.) pg 2				
Furthe	er documents are listed in the continuation of Box C.				
* Special categories of cited documents: "A" document defining the general state of the art which is not considered date and not in conflict with the application but cited to understand					
	f particular relevance application or patent but published on or after the international ate	"X" document of particular relevance; the considered novel or cannot be considered.	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive		
"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) "O" document referring to an oral disclosure, use, exhibition or other means		step when the document is taken alone "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 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			ch report		
17 Sep 2008 (17.09.2008) 23 SFP 2008			}		
Name and n	nailing address of the ISA/US	Authorized officer:			
	T, Attn: ISA/US, Commissioner for Patents 50, Alexandria, Virginia 22313-1450	Lee W. Young			
Facsimile No. 571-273-3201		PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774			