

(19) World Intellectual Property Organization  
International Bureau



(43) International Publication Date  
24 July 2008 (24.07.2008)

PCT

(10) International Publication Number  
**WO 2008/089268 A3**

(51) International Patent Classification:

*A61K 33/20* (2006.01)    *A61P 11/04* (2006.01)  
*A61K 33/00* (2006.01)    *A61P 17/02* (2006.01)  
*A61P 11/00* (2006.01)    *A61P 29/00* (2006.01)

(21) International Application Number:

PCT/US2008/051208

(22) International Filing Date: 16 January 2008 (16.01.2008)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

60/885,122                      16 January 2007 (16.01.2007)    US

(71) Applicant (for all designated States except US): **PURICORE, INC.** [US/US]; 508 Lapp Road, Malvern, PA 19355 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **GOLDAN, Keith** [-/US]; Downingtown, PA (US). **SAMPSON, Claire** [-/US]; Doylestown, PA (US).

(74) Agents: **HAYMAN, Mark L.** et al; Cooley Godward Kronish LLP, 777 6th Street, NW, Suite 1100, Washington, DC 20001 (US).

(81) Designated States (unless otherwise indicated, for every kind of national protection available):

AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, **BR**, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, 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, LY, MA, MD, ME, 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, HR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, NO, 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

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

16 October 2008

(54) Title: METHODS AND COMPOSITIONS FOR TREATING CONDITIONS ASSOCIATED WITH INFECTION AND/OR INFLAMMATION

(57) Abstract: The present invention provides methods and compositions for treating and preventing conditions characterized by infection and/or inflammation, especially of the eyes, ears, nose, and/or throat. The methods of the invention involve administering hypohalous acid to the patient, such as in the form of a composition described herein.



**WO 2008/089268 A3**

## INTERNATIONAL SEARCH REPORT

International application No

PCT/US08/51208

<b>A CLASSIFICATION OF SUBJECT MATTER</b>		
IPC <b>A61K 33/20(2006 01),33/00(2006 01),A61P 11/00(2006 01),H/04(2006 01),17/02(2006 01),29/00(2006 01)</b>		
USPC 424/66 1,665,667,673,723,5 14/912		
According to International Patent Classification (IPC) or to both national classification and IPC		
<b>B FIELDS SEARCHED</b>		
Minimum documentation searched (classification system followed by classification symbols) U S 424/661, 665, 667, 673, 723, 5 14/912		
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) Please See Continuation Sheet		
<b>C DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No
X --- Y	US 2004/0208940 A (SELKON) 21 October 2004 (21 10 2004), paragraphs 4, 18-29, 48, claims 1, 7-10, 16-18	1, 4, 10, 18-22, 24 ----- 1-2, 4-22, 24
X --- Y	US 2004/006281 8 A (CALDERON) 01 April 2004 (01 04 2004), paragraphs 20, 27-28, 63, claims 2 and 4	1-2, 18-19, 22-23 ----- 1-2, 18-19, 22-23
Y	Database DERWENT on WEST (USPTO), London Derwent Publications Ltd, AN 1998-537385, JP 10236961 A (NOBEL IGAKU KENKYUSHO YG), abstract	1-4, 10-13, 19
<input type="checkbox"/> Further documents are listed in the continuation of Box C <input type="checkbox"/> See patent family 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 cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance, the claimed invention cannot be considered novel <i>or</i> cannot be considered to involve an inventive step when the document is taken alone
"E" earlier application or patent published on or after the international filing date	"Y"	<i>document</i> 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
"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 <i>reason</i> (as specified)	"&"	document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition <i>or other means</i>		
"P" document published prior to the international filing date but later than the priority date claimed		
Date of the actual completion of the international search 15 July 2008 (15 07 2008)	Date of mailing of the international search report <b>08 AUG 2008</b>	
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 (571) 273-3201	Authorized officer <i>John Pak</i> Telephone No (571)272-0500	

# INTERNATIONAL SEARCH REPORT

International application No

PCT/US08/51208

## Box No. 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  Claims Nos  
because they relate to subject matter not required to be searched by this Authority, namely
  
- 2  L J 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 No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows  
Please See Continuation 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 additional fees, this Authority did not invite payment of any additional fees
  - 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  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
- Remark on Protest**
- The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee
  - I The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation
  - J No protest accompanied the payment of additional search fees

**BOX III. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING**

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13 1 .

Group I, claims 1-22 (in part), drawn to method for treating a condition characterized by infection and/or inflammation of the eye

Group II, claims 1-2, 4-23 (in part), drawn to method for treating a condition characterized by infection and/or inflammation of the ear

Group III, claims 1-2, 4-23, drawn to method for treating a condition characterized by infection and/or inflammation of the nose, mouth or throat

Group IV, claim 24, drawn to a composition comprising electrolyzed saline consisting essentially of hypochlorous acid, pH 4-7, 50-1000 ppm available free chlorine content, with a pharmaceutically acceptable buffer and/or carrier

The inventions listed as Groups I to IV do not relate to a single general inventive concept under PCT Rule 13 1 because, under PCT Rule 13 2, they lack the same or corresponding special technical features for the following reasons

Under lack of unity rules, unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" is defined as meaning those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art. The "contribution over the prior art" is considered with respect to novelty and inventive step.

Here, the composition features are not even required by the method inventions (Groups I, II and III), and moreover, the composition is anticipated by Selkon (US 2004/0208940, see paragraphs 4, 18, 25-26, 48, claims 1, 7-10, 16-18). Hence, there can be no requisite special technical feature for unity of invention because there is no feature in the composition invention (Group IV) that makes a contribution over the prior art.

As for the three separate method inventions (Groups I, II, III), they are each directed to treating different conditions. Treating the eye is distinct from treating the ear or nose/mouth/throat. Treating the ear is distinct from treating the eye or nose/mouth/throat. Treating the nose, mouth or throat is distinct from treating the eye or ear. Derwent abstract 1998-537385 is sufficient evidence that treating the eye with a hypochlorous acid solution as claimed herein does not make a contribution over the prior art. Said abstract is also sufficient evidence that prior art teaching or disclosing one condition does not necessarily teach or suggest the other conditions.

For these reasons, the four inventions as set forth above do not relate to a single general inventive concept because they lack the same or corresponding special technical features.

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US08/5 1208

Continuation of B. FIELDS SEARCHED Item 3:

WEST, Files PGPUB, USPAT, DERWENT. Search Terms: hypochlorous acid, eye, ear, nose, mouth, throat, conjunctivitis, rhinitis, rhinorrhea, nasal, otitis, pharyngitis, stomatitis.