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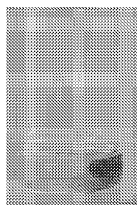
- (51) **International Patent Classification:**  
*A61K 9/08* (2006.01)      *A61K 31/015* (2006.01)  
*A61K 9/06* (2006.01)      *A61P 27/16* (2006.01)  
*A61K 9/46* (2006.01)
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61/292,926      7 January 2010 (07.01.2010)      US
- (63) **Related by continuation (CON) or continuation-in-part (CIP) to earlier application:**  
US      61/292,926 (CIP)  
Filed on      7 January 2010 (07.01.2010)
- (71) **Applicant** (for all designated States except US): **ORA, INC.** [US/US]; 300 Brickstone Square, Andover, MA 01810 (US).
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- (75) **Inventors/Applicants** (for US only): **SHAPIRO, Aron, M.** [US/US]; 27 Ossipee Rd, #1, Somerville, MA 02144 (US). **FRIEDENSOHN, Peter, N.** [US/US]; 398 Ather-ton St., Milton, MA 02186 (US). **MENARD, Leo, P.** [US/US]; 31 A Jay St., Cambridge, MA 02139 (US). **LYNCH, Stephanie, K.** [US/US]; 15 Sheep Farm Dr., East Greenwich, RI 02818 (US). **MINNO, George, E.** [US/US]; 17 Duston Road, Windham, NH 03087 (US). **NICE, Jacquelyn, M.** [US/US]; 75 Hume Ave, Medford, MA 02155 (US).
- (74) **Agents:** **ELRIFI, Ivor, R.** et al.; Mintz Levin Cohn Fer-ris Glovsky And Popeo, P.C., One Financial Center, Boston, MA 02111 (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,

[Continued on next page]

(54) **Title:** FORMULATIONS AND METHODS FOR DISSOLVING CERUMEN

Figure 1

Cerumen samples in limonene

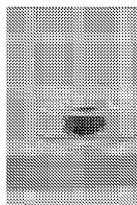


T = 1 minute

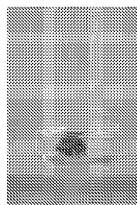


T = 15 minutes

Cerumen samples in carbamide peroxide (active ingredient in Debrox® and Murine® products)



T = 1 minute



T = 15 minutes

(57) **Abstract:** Formulations, kits, and methods are described herein for relieving symptoms and complications from excessive or impacted cerumen. The formulations comprise effective amounts of limonene, one or more bile salts, and/or sodium bi-carbonate.



CA, CH, CL, 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, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

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LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

**Published:**

- with international search report (Art. 21(3))
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))

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

24 November 2011

## INTERNATIONAL SEARCH REPORT

International application No.  
**PCT/US2011/020453****A. CLASSIFICATION OF SUBJECT MATTER***A61K 9/08(2006.01)i, A61K 9/06(2006.01)i, A61K 9/46(2006.01)i, A61K 31/015(2006.01)i, A61P 27/16(2006.01)i*

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 9/08; A61K 9/14; A61K 31/365; A61P 27/16; A61K 31/18; A61K 31/415; A61K 31/56; A61K 31/785; A61K 31/47; A61K 31/57; A61K 33/00; A61K 9/66

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Korean utility models and applications for utility models

Japanese utility models and applications for utility models

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

eKOMPASS(KIPO internal) &amp; Keywords: limonen, bile salt, bicarbonate, cerumenolytic, cerumen, ear canal

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6417179 B1 (C. G. BURKHART and C. N. BURKHART) 09 July 2002	2,50,52,55
Y	See abstract, claim 1 and column 1.	4,5,53,57
X	US 2004-0126436 A1 (G. D. CAGLE et al.) 01 July 2004	3,51,56
Y	See abstract, paragraphs [0010], [0025]-[0031], [0064], [0065], Table 1 and all claims.	4,5,53,57
A	US 2005-0113409 A1 (J. R. CONNOR and P. T. MANNING) 26 May 2005	1,49,54
	See abstract and paragraphs [0224], [0244], [0252], [0255] and [0264].	
A	US 2008-0167281 A1 (D. M. PRESTON) 10 July 2008	1,49,54
	See abstract and paragraphs [0044], [0045] and [0047].	
A	US 2004-0204471 A1 (K. SEIBERT) 14 October 2004	1,49,54
	See abstract, claim 1, 12 and paragraph [1315].	



Further documents are listed in the continuation of Box C.



See patent family annex.

\* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of citation or other special reason (as specified)

"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

"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

"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

"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

"&amp;" document member of the same patent family

Date of the actual completion of the international search

21 SEPTEMBER 2011 (21.09.2011)

Date of mailing of the international search report

**21 SEPTEMBER 2011 (21.09.2011)**

Name and mailing address of the ISA/KR

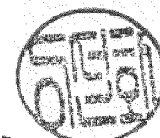
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**INTERNATIONAL SEARCH REPORT**

International application No.

**PCT/US2011/020453****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.: 18-48  
because they relate to subject matter not required to be searched by this Authority, namely:  
Claims 18-48 are directed to a treatment method of the human body by therapy and thus relate to a subject matter which this International Searching Authority is not required to search under Article 17(2)(a)(i) of the PCT and Rule 39.1(iv) of the Regulations under the PCT.
2. ☒ Claims Nos.: 15,16,47,48  
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:  
Claims 15, 16, 47 and 48 are unclear under PCT Article 6, because they refers to anyone of claims 14 or 46 which are not drafted in accordance with the second and third sentences of PCT Rule 6.4(a).
3. ☒ Claims Nos.: 6-14,17,28-32,42-46,58  
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:

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. ☐ 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.
- ☐ 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.
- ☐ No protest accompanied the payment of additional search fees.

**INTERNATIONAL SEARCH REPORT**

Information on patent family members

International application No.

**PCT/US2011/020453**

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 6417179 B1	09.07.2002	US 6524602 B1	25.02.2003
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		EP 1337228 A2	27.08.2003
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		WO 2005-023189 A3	10.08.2006
US 2008-0167281 A1	10.07.2008	None	
US 2004-0204471 A1	14.10.2004	None	