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(54) Title: CONTROLLED-RELEASE CNS MODULATING COMPOSITIONS AND METHODS FOR THE TREATMENT OF OTIC DISORDERS

(57) Abstract: Disclosed herein are compositions and methods for the treatment of otic disorders with CNS modulating agent compositions and compositions administered locally to an individual afflicted with an otic disorder, through direct application of these compositions and compositions onto or via perfusion into the targeted auris structure(s).


(Continued on next page)
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, MK, 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).  

— as to the applicant’s entitlement to claim the priority of the earlier application (Rule 4.17(U))  

Published:  
— with international search report (Rule 48.2(h))  
— 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))  

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A. CLASSIFICATION OF SUBJECT MATTER

A61K 9/06(2006.01)i, A61P 27/16(2006.01)i, A61K 9/14(2006.01)i, A61K 9/16(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)
IPC A61K

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
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<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No</th>
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<td>X</td>
<td>US 6316011 B1 (Hon, E S. et al) 13 November 2001 See abstract, col. 1 l 12-18, col. 7 l 25-42; col. 7 1.63-col.8 1.4; col 17 l 11-28, examples, claims</td>
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<td>US 2004-0101560 A1 (Sawchuk, R.J. et al) 27 May 2004 See abstract, paragraph [0016], [0017], [0020], [0032], examples, claims</td>
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<td>X</td>
<td>LEE, S.H. et al &quot;Regional delivery of vancomycin using Pluronic F-127 to inhibit methicillin resistant Staphylococcus aureus (MRSA) growth in chronic otitis media in vitro and in vivo&quot; Journal of Controlled Release 2004 vol 96, pp. 1-7, ISSN 0168-3659 See abstract, Materials and Methods, Figure 2, Result and Discussion</td>
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Further documents are listed in the continuation of Box C See patent family annex

Date of the actual completion of the international search 11 MARCH 2010 (11.03.2010)
Date of mailing of the international search report 12 MARCH 2010 (12.03.2010)

Name and mailing address of the ISA/KR

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Form PCT/ISA/210 (second sheet) (My 2008)
INTERNATIONAL SEARCH REPORT

**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. [Y] Claims Nos 19-21  
   because they relate to subject matter not required to be searched by this Authority, namely
   Claims 19-21 pertain to methods for treatment of the human by therapy and thus relate to a subject matter which this International Searching Authority is not required, under Article 17(2)(a)(i) of the PCT and Rule 39 l(iv) of the Regulations under the PCT, to search.

2. [ ] 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 64(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.

Form PCT/ISA/210 (continuation of first sheet (2)) (July 2008)
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