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- (21) International Application Number:  
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61/578,755 21 December 2011 (21.12.2011) US
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- (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, BN, BR, BW, BY, BZ, 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, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, 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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Declarations under Rule 4.17:

- as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))
- as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))

Published:

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

24 July 2014

(54) Title: TRANSMUCOSAL DRUG DELIVERY DEVICES FOR USE IN CHRONIC PAIN RELIEF

### Study Design Schematic

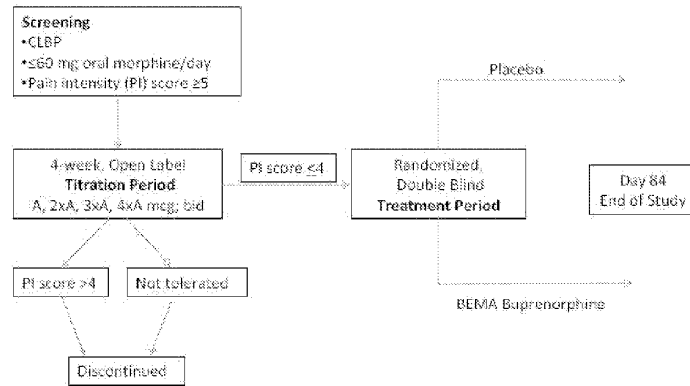


Figure 1.

(57) Abstract: Provided herein are methods for treating chronic pain by administering low doses of buprenorphine twice daily (or once daily) via a transmucosal drug delivery device. The methods and devices efficiently treat chronic pain without significant side effects. In one embodiment, the buprenorphine delivery device comprises a bioerodable mucoadhesive layer comprising a therapeutically effective amount of buprenorphine disposed in a buffered polymeric diffusion environment, wherein the polymeric diffusion environment is a buffered environment having a pH of between about 4 and about 6.

WO 2013/096811 A3

INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US2012/071330

<p><b>A. CLASSIFICATION OF SUBJECT MATTER</b>                  IPC(8) - A61K 9/70 (2013.01)                  USPC - 424/435                  According to International Patent Classification (IPC) or to both national classification and IPC</p>																	
<p><b>B. FIELDS SEARCHED</b></p> <p>Minimum documentation searched (classification system followed by classification symbols)                  IPC(8) - A61K 9/70, 31/44, 31/485; A61P 25/04, 25/30 (2013.01)                  USPC - 424/422, 434, 435, 444; 514/279, 282</p> <p>Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched                  CPC Class/Subclass(es): A61K 9/0053, 9/006</p> <p>Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)                  PatBase, Google Patents, Pubmed</p>																	
<p><b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b></p> <table border="1"> <thead> <tr> <th>Category*</th> <th>Citation of document, with indication, where appropriate, of the relevant passages</th> <th>Relevant to claim No.</th> </tr> </thead> <tbody> <tr> <td>X</td> <td>US 2011/0262522 A1 (FINN et al) 27 October 2011 (27.10.2011) entire document</td> <td>1-3, 14-19</td> </tr> <tr> <td>A</td> <td>US 2011/0189259 A1 (VASISHT et al) 04 August 2011 (04.08.2011) entire document</td> <td>1-3, 14-19</td> </tr> <tr> <td>A</td> <td>US 2004/0024003 A1 (ASMUSSEN et al) 05 February 2004 (05.02.2004) entire document</td> <td>1-3, 14-19</td> </tr> <tr> <td>A</td> <td>US 2009/0270438 A1 (BOOLES et al) 29 October 2009 (29.10.2009) entire document</td> <td>1-3, 14-19</td> </tr> </tbody> </table>			Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.	X	US 2011/0262522 A1 (FINN et al) 27 October 2011 (27.10.2011) entire document	1-3, 14-19	A	US 2011/0189259 A1 (VASISHT et al) 04 August 2011 (04.08.2011) entire document	1-3, 14-19	A	US 2004/0024003 A1 (ASMUSSEN et al) 05 February 2004 (05.02.2004) entire document	1-3, 14-19	A	US 2009/0270438 A1 (BOOLES et al) 29 October 2009 (29.10.2009) entire document	1-3, 14-19
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<p><input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/></p>																	
<p>* Special categories of cited documents:</p> <table border="0"> <tr> <td>"A" document defining the general state of the art which is not considered to be of particular relevance</td> <td>"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</td> </tr> <tr> <td>"E" earlier application or patent but published on or after the international filing date</td> <td>"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</td> </tr> <tr> <td>"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)</td> <td>"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</td> </tr> <tr> <td>"O" document referring to an oral disclosure, use, exhibition or other means</td> <td>"&amp;" document member of the same patent family</td> </tr> <tr> <td>"P" document published prior to the international filing date but later than the priority date claimed</td> <td></td> </tr> </table>			"A" 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 application or patent but published on or after the international filing date	"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	"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 being obvious to a person skilled in the art	"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family	"P" document published prior to the international filing date but later than the priority date claimed						
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<p>Date of the actual completion of the international search 11 February 2013</p>		<p>Date of mailing of the international search report <b>22 FEB 2013</b></p>															
<p>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</p>		<p>Authorized officer:                  Blaine R. Copenheaver                  PCT Helpdesk: 571-272-4300                  PCT OSP: 571-272-7774</p>															

Form PCT/ISA/210 (second sheet) (July 2009)

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2012/071330

**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.  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.: 4-13, 20  
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 additional fees, this Authority did not invite payment of 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.
- 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 2009)