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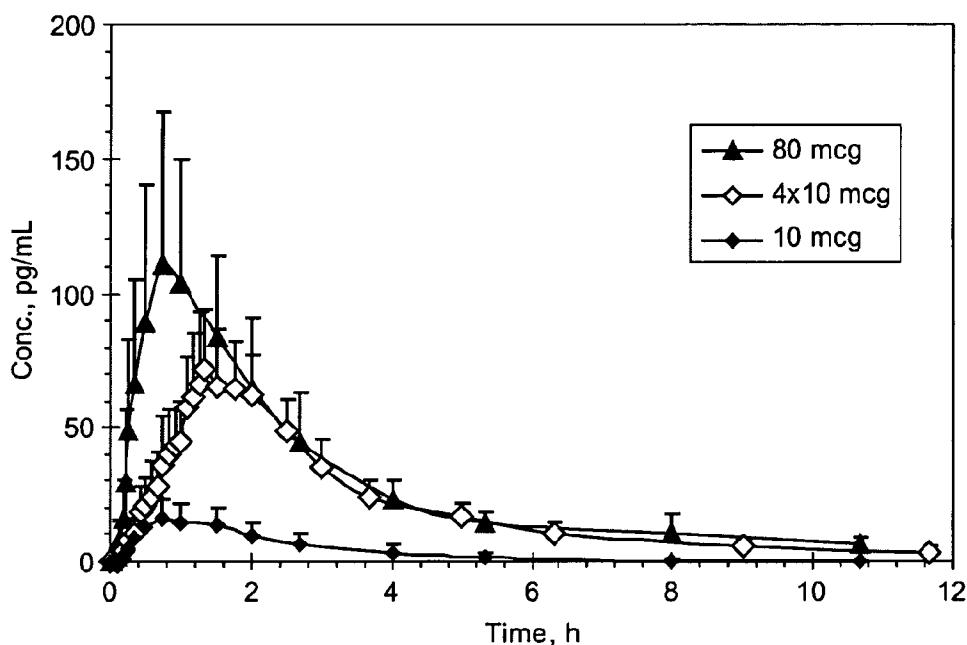
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(81) **Designated States** (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FT, GB, GD, GE, 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

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[Continued on next page]

(54) **Title:** SMALL VOLUME ORAL TRANSMUCOSAL DOSAGE FORMS CONTAINING SUFENTANIL FOR TREATMENT OF PAIN



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(57) **Abstract:** Compositions, methods and systems for administration of small volume sufentanil-containing drug dosage forms to the oral mucosa of a subject are disclosed.



FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, MT, 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).

— before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

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INTERNATIONAL SEARCH REPORT

International application No
PCT/US2007/089018

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61K9/70 C07D211/58

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

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 practical, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 01/30288 A (ANESTA CORP [US]) 3 May 2001 (2001-05-03) page 2, lines 12-23; claims 27-52 page 8, lines 22-34 ----- WO 2004/069198 A (CEPHALON INC [US]; HAGUE BRIAN [US]; MALAND LYNN J [US]) 19 August 2004 (2004-08-19) page 3, lines 7-15, 30-32 page 14, line 19 ----- US 6.216 033 B1 (SOUTHAM MARY [US] ET AL) 10 April 2001 (2001-04-10) column 1, lines 22-30; claims 10-15; figure 1 column 3, lines 34-43 column 4, line 65 - column 5, line 10 ----- -/-	1-27, 58-63 1-27, 58-63 1-27, 58-63
A		

Further documents are listed in the continuation of Box C.

See patent family annex.

* Special categories of cited documents :

^{1A}" document defining the general state of the art which is not considered to be of particular relevance

^{1E}" earlier document but published on or after the international filing date

^{1L}" 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)

^{1O}" document referring to an oral disclosure, use, exhibition or other means

^{1P}" document published prior to the international filing date but later than the priority date claimed

^{1T}" 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

^{1X}" 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

^{1Y}" 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.

^{1&}" document member of the same patent family

Date of the actual completion of the international search

Date of mailing of the international search report

19 August 2008

15/10/2008

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INTERNATIONAL SEARCH REPORT

International application No
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(^Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2005/129737 A1 (JOHNSON RANDOLPH M [US] ET AL) 16 June 2005 (2005-06-16) paragraph [0084] -----	1-27, 58-63

FURTHER INFORMATION CONTINUED FROM PCTASA/ 210

Continuation of Box II. 1

The claims 34-57 are directed to a method of treatment of the human/animal body. The search based on the alleged effects of the compound/composition is included in that for claims 1-27

Continuation of Box II. 1

Claims Nos. : -

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

INTERNATIONAL SEARCH REPORTInternational application No.
PCT/US2007/089018**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:
see FURTHER INFORMATION sheet PCT/ISA/210
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 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:

see additional 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 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.:

see annex

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.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-21, 58-63

oral transmucosal sufentanil formulation

2. claims: 22-33

single dose applicators or drug dispensing devices

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2007/089018

Patent document cited in search report	Publication date	Patent family member(s)			Publication date
WO 0130288	A 03-05-2001	AU 1079701	A	08-05-2001	
		CA 2388610	A1	03-05-2001	
		EP 1242013	A1	25-09-2002	
		OP 2003512402	T	02-04-2003	
		JP 2008201805	A	04-09-2008	
		MX PA02004235	A	21-04-2004	
		US 6264981	B1	24-07-2001	
WO 2004069198	A 19-08-2004	AU 2004208827	A1	19-08-2004	
		BR PI0406996	A	10-01-2006	
		CA 2515025	A1	19-08-2004	
		EP 1596836	A2	23-11-2005	
		JP 2006516648	T	06-07-2006	
		KR 20050105198	A	03-11-2005	
		MX PA05008278	A	31-05-2006	
		US 2004253307	A1	16-12-2004	
US 6216033	B1 10-04-2001	NONE			
US 2005129737	A1 16-06-2005	US 2004157884	A1	12-08-2004	
		US 2008161356	A1	03-07-2008	
		US 2008161357	A1	03-07-2008	