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(54) Title: SUSTAINED RELEASE PARENTERAL FORMULATIONS OF BUPRENORPHINE

(57) Abstract: An oil-in-water buprenorphine formulation including buprenorphine and a surfactant that emulsifies the buprenorphine in oil, wherein the drug release is controlled by varying the oil concentration and/or pH. A buprenorphine aqueous suspension formulation including a free base buprenorphine and a suspension stabilizer. A buprenorphine oil formulation including a buprenorphine salt suspended in a pharmaceutically acceptable oil. Methods of providing sustained release of buprenorphine over a period of time.



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INTERNATIONAL SEARCH REPORT

International application No

PCT/US2008/055211

A. CLASSIFICATION OF SUBJECT MATTER INV. A61K9/00 A61K9/24 A61K47/44 A61K31/485		
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, EMBASE, FSTA		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DATABASE WPI Week 199539 Thomson Scientific, London, GB; AN 1995-299497 XP002487837 & JP 07 196510 A (NIPPON SEIYAKU KK) 1 August 1995 (1995-08-01) abstract example 1	1-8, 20
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-/-		
☒ 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 "E" earlier document 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 another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means 1P ¹ 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 ¹ " 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. "&" document member of the same patent family		
Date of the actual completion of the international search 14 July 2008		Date of mailing of the international search report 15/10/2008
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL- 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax (+31-70) 340-3016		Authorized officer Schüle, Stefanie

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2008/055211

^Continuation).. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with Indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 229 130 A (SHARMA KULDEEPAK [US] ET AL) 20 July 1993 (1993-07-20) claims 1-7	1-8,20
A	JP 2004 175706 A (CHI MEI FOUNDATION MEDICAL CT) 24 June 2004 (2004-06-24) example 1	1-8,20
A	EP 0 368 409 A (NORWICH EATON PHARMA [US]) 16 May 1990 (1990-05-16) example V claim 1	1-8,20
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P,X	WO 2007/103185 A (UNIV TENNESSEE RES FOUNDATION [US]; SHUKLA ATUL J [US]; JOHNSON JAMES) 13 September 2007 (2007-09-13) page 15, line 14 - page 16, line 12 page 17, line 23 - line 32	1-8,20

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2008/055211

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:

Although claim 20 is directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
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 allsearchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an 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 reportcovers 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: 1-8, 20 (part .)

Oil-in-water compositions comprising buprenorphine and a surfactant

2. claims: 9-15, 20 (part .)

Aqueous suspensions comprising free base buprenorphine and a suspending agent

3. claims: 16-19, 20 (part.)

Oil formulation comprising buprenorphine salt and a pharmaceutically acceptable oil

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2008/055211

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