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(54) Title: MULTI-STEP METHOD OF PAIN AND/OR INFLAMMATION TREATMENT

(57) Abstract: The present invention provides multi-step methods for treating pain and/or inflammation. In a preferred embodiment, the method comprises administering to a patient in need of relief of pain and/or inflammation the following three components: (1) a skin penetration enhancer; (2) a daytime analgesic; and (3) a nighttime joint and muscle rejuvenator. The present invention also provides an analgesic composition comprising PHYTOLANE LS® and garlic oil, preferably in a cream or ointment base.



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## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 08/70452

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61K 36/00; A61K 9/06; A61K 31/00 (2008.04)

USPC - 424/725; 514/557; 514/1

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)

USPC - 424/725; 514/557; 514/1; see keywords below.

IPC(8) - A61K 36/00; A61K 9/06; A61K 31/00 (2008.04)

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 practicable, search terms used)

PubWEST (DB=PGPB,USPT,USOC,EPAB,JPAB; PLUR=NO; OP=ADJ); freepatentsonline.com; WIPO; Google Patents; Google;

Keywords: daytime, nighttime, muscle, rejuvenator, arthritis, bryonia, rhus toxicodendron, squalane, squalene, shark liver oil, penetration enhancer, devil's turnip, poison ivy, chronotherapy, chronobiology, jojoba

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X ---	FREEMAN. Natural Relief 1222: An All-Natural Analgesic Cream Provides Effective Topical Pain Relief. LE Magazine, 2006 [online]. [Retrieved on 09 December 2008 (09.12.2008)]. Retrieved from the internet: <URL: <a href="http://www.lef.org/magazine/mag2006/aug2006_report_natural_01.htm">http://www.lef.org/magazine/mag2006/aug2006_report_natural_01.htm</a> (pg 1, para 3 and 7; pg 2, para 6 and 7; pg 3, para 2 and 4-8; pg 4, para 1 and 6)	14 ----- 1-13, 15 and 16
Y	WO 2007/066149 A2 (STANIFORTH et al) 14 June 2007 (14.06.2007): pg 4, para 3, para 5, pg 8, para 2, pg 14, para 1, para 3, pg 15, para 1, pg 16, para 3, pg 18, para 4; p 27, ln 27-30.	1-13, 15 and 16
Y	US 2004/0166183 A1 (RUSELER-VAN EMBDEN et al) 26 August 2004 (26.08.2004): para [0057]-[0058], [0061], [0063], [0070]	6
Y	US 2004/0151793 A1 (PASPALEEVA-KUHN et al) 5 August 2004 (05.08.2004) [0001], [0023], [0026], [0034], [0053], [0070], [0076], [0079], [0110], [0113]-[0114], [0122]-[0123], [0131], [0138], [0147], [0156]-[0157], [0160], [0162]-[0163], [0170] and [0179]	6



Further documents are listed in the continuation of Box C.



\* 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 another 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

09 December 2008 (09.12.2008)

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# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 08/70452

## 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.:  
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 Supplemental 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.:  
1-16

### 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/US 08/70452

Supplemental Sheet.

Continuation of Box III. Lack of Unity of Invention.

This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group 1, claims 1-16, drawn to a method (and kit) for treating pain/inflammation in a patient, utilizing

- a) a skin penetration enhancer
- b) a daytime analgesic
- c) nighttime joint and muscle rejuvenator

Group 2, claims 17-32, drawn to a composition (and method of preparing the composition) containing a topical analgesic comprising Phytolane and garlic oil, wherein the preparation steps including the use of a polymer emulsion, and additional components such as reticulin and elastin.

The inventions listed as Groups 1 and 2 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features, or shared technical features that are novel or a contribution over the prior art.

Group 1, drawn to a method of treating pain and inflammation, utilizes multiple components including an analgesic, to achieve a chronopharmacological treatment of the patient. Group 1 does share a common feature with Group 2, namely the use of a topically applied analgesic. However, with respect to the independent claims of Group 1, squalane (i.e. Phytolane) is not specifically set forth as the daytime analgesic. Furthermore, Group 1 does not specifically iterate a compositional listing (for instance, contrary to claim 21, as an independent claim member of Group 2). Group 1 also does not specifically disclose mixing order or steps to form a topical analgesic, as for example, is the case for claims 27 and 29 of Group 2.

Group 2, drawn to topical analgesic compositions, discloses various methods to form the specific composition. Group 2 does also incorporate the use of an analgesic for treatment of pain or inflammation, as does Group 1. Group 2, as a defining technical feature, claims the use of Phytolane (squalane or shark liver oil) and garlic oil, polymer emulsions, reticulin, and elastin, features not present in Group 1, as set forth in the independent claims. However, Group 2 does not utilize a specific chronopharmacological method, i.e. a daytime and nighttime application for treatment. Additionally, Group 2 does not specifically disclose the use of a nighttime joint and muscle rejuvenator. Although Phytolane in combination with garlic oil may be utilized as an analgesic or anti-inflammatory, it does not constitute a special technical feature sufficient to maintain unity of invention between Group 1 and Group 2, as its use as a topical analgesic is well-known in the art.

For instance, US 5,032,400 A to Wiersum et al (hereinafter Wiersum) 16 July 1991 (16.07.1991) discloses the use of shark liver oil and garlic oil in a topical analgesic, or as an anti-inflammatory agent / joint pain remediator (col 1, ln 32-35, ln 55-68). Essentially, Wiersum anticipates the use of squalane and garlic oil as a topical analgesic, negating the use thereof as a possible special technical feature in association with elements a, b, or c of Group 1 (as previously set forth above). Thus, as a result of the aforementioned reasons, Groups 1 and 2 fail to maintain unity of invention and are therefore, not in accordance with PCT Rule 13.2.