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(71) Applicant (for all designated States except US): **CSI GMBH** [DE/DE]; Untere Uferstabe 21, 73614 Schorndorf (DE).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **CALDWELL, Larry J.** [US/US]; 4146 Cranford Circle, San Jose, California 95124 (US). **SHIRAI, Sadanobu** [JP/JP]; 1591-15 Tahishimo-machi, Takamatsu-shi, Kagawa 761-8075 (JP).

(74) Agent: **FIELD, Bret E.**; Bozicevic, Field & Francis LLP, 1900 University Avenue, Suite 200, East Palo Alto, California 94303 (US).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM,

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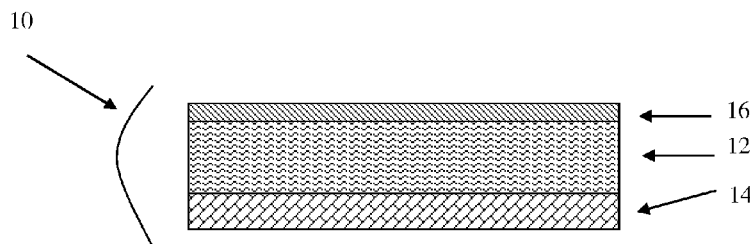
- with international search report (Art. 21(3))
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))

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

20 September 2012

(54) Title: EXTENDED-RELEASE BETA AGONIST/ANTICHOLINERGIC TRANSDERMAL PATCHES AND METHODS FOR USING THE SAME

FIGURE 1



(57) Abstract: Extended-release beta agonist/anticholinergic transdermal patches are provided. Transdermal patches have an adhesive matrix which includes both a beta agonist, e.g., tulobuterol, and an anticholinergic, e.g., scopolamine, where the matrix is configured to be storage-stable and provide for extended release of the beta agonist and anticholinergic. Aspects of the invention further include methods of using the transdermal patches, e.g., in the treatment of pulmonary conditions, such as chronic obstructive pulmonary disease (COPD).



WO 2012/103016 A3

**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.: 20, 21  
because they relate to subject matter not required to be searched by this Authority, namely:  
Claims 20 and 21 are directed to a treatment method of the human body by therapy and thus relate to a subject matter which this International Searching Authority is not required to search under Article 17(2)(a)(i) of the PCT and Rule 39.1(iv) of the Regulations under the PCT.
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:

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.

**A. CLASSIFICATION OF SUBJECT MATTER***A61K 9/70(2006.01)i, A61K 47/30(2006.01)i, A61P 11/00(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)

A61K 9/70; A61L 15/44; A61K

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

Korean utility models and applications for utility models

Japanese utility models and applications for utility models

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

eKOMPASS(KIPO internal) &amp; Keywords: topical, patch, transdermal, tulobuterol, beta agonist, COPD, anticholinergic, scopolamine, rubber, adhesive, styrene-butadiene block copolymer, styrene-isoprene block copolymer, fatty acid, resin, backing, release liner, extended-release

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2005-0220852 A1 (S. SHIRAI et al.) 06 October 2005 See abstract, paragraphs [0018], [0024], [0026], [0028], [0032], examples 1-4, and claims 1-3.	1-19,22
Y	WO 2005-046600 A2 (NEXMED HOLDINGS, INC.) 26 May 2005 See abstract, lines 1-2, 16-18 in p. 9, lines 15-16 in p. 13, examples 16-25, and all claims.	1-19,22
Y	EP 0439180 A2 (LTS LOHMANN THERAPIE-SYSTEME GMBH & CO. KG.) 31 July 1991 See abstract, lines 16-51 in p. 3, examples 2, 2a, 5, 6, and all claims.	1-19,22
Y	US 06117447 A (Y. NAKANO et al.) 12 September 2000 See abstract, lines 44-49 in column 2, lines 12-36 in column 4, examples 6-8, and all claims.	1-19,22
Y	K. AKAMATSU et al., "Improvement of pulmonary function and dyspnea by tiotropium in COPD patients using a transdermal beta2-agonist", Pulmonary Pharmacology & Therapeutics, Vol. 20, pp. 701-707, 2007 See abstract and Fig. 2.	1-19,22

 Further documents are listed in the continuation of Box C. See patent family annex.

\* 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 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

18 JULY 2012 (18.07.2012)

Date of mailing of the international search report

**20 JULY 2012 (20.07.2012)**

Name and mailing address of the ISA/KR

Korean Intellectual Property Office  
189 Cheongsu-ro, Seo-gu, Daejeon Metropolitan  
City, 302-701, Republic of Korea

Facsimile No. 82-42-472-7140

Authorized officer

LEE, SUN HWA

Telephone No. 82-42-481-5606



**INTERNATIONAL SEARCH REPORT**

International application No.

**PCT/US2012/022233**

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	M. ICHINOSE et al., "Additive effects of transdermal tulobuterol to inhaled tiotropium in patients with COPD", Respiratory Medicine, Vol. 104, pp. 267-274, 2010 See summary.	1-19,22

**INTERNATIONAL SEARCH REPORT**

Information on patent family members

International application No.

**PCT/US2012/022233**

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