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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 13/071,497   | 03/24/2011  | Daniel H. Lee        | TS-02-313U3         | 4143             |
| 30349  | 7590        | 05/10/2013           | EXAMINER            |                  |
| JACKSON & CO., LLP<br>6114 LA SALLE AVENUE<br>#507<br>OAKLAND, CA 94611-2802 |             |                      | MCEVOY, THOMAS M    |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 3731                |                  |
|  |             |                      | NOTIFICATION DATE   | DELIVERY MODE    |
|  |             |                      | 05/10/2013          | ELECTRONIC       |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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|                              |                                      |                                   |  |
|------------------------------|--------------------------------------|-----------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>13/071,497 | <b>Applicant(s)</b><br>LEE ET AL. |  |
|                              | <b>Examiner</b><br>THOMAS MCEVOY     | <b>Art Unit</b><br>3731           | <b>AIA (First Inventor to File) Status</b><br>No |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1)  Responsive to communication(s) filed on 14 January 2013.  
 A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on \_\_\_\_\_.
- 2a)  This action is **FINAL**.                      2b)  This action is non-final.
- 3)  An election was made by the applicant in response to a restriction requirement set forth during the interview on \_\_\_\_\_; the restriction requirement and election have been incorporated into this action.
- 4)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 5)  Claim(s) 6-15 is/are pending in the application.  
5a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 6)  Claim(s) \_\_\_\_\_ is/are allowed.
- 7)  Claim(s) 6-15 is/are rejected.
- 8)  Claim(s) \_\_\_\_\_ is/are objected to.
- 9)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

\* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see [http://www.uspto.gov/patents/init\\_events/pph/index.jsp](http://www.uspto.gov/patents/init_events/pph/index.jsp) or send an inquiry to [PPHfeedback@uspto.gov](mailto:PPHfeedback@uspto.gov).

**Application Papers**

- 10)  The specification is objected to by the Examiner.
- 11)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

**Priority under 35 U.S.C. § 119**

- 12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

**Certified copies:**

- a)  All    b)  Some \*    c)  None of the:
1.  Certified copies of the priority documents have been received.
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Interim copies:**

- a)  All    b)  Some    c)  None of the: Interim copies of the priority documents have been received.

**Attachment(s)**

- 1)  Notice of References Cited (PTO-892)
- 2)  Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 5/17/2011, 1/18/2012.
- 3)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 4)  Other: \_\_\_\_\_.

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election without traverse of Invention II in the reply filed on January 14<sup>th</sup> 2013 is acknowledged.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of 35 U.S.C. 112(a):  
(a) IN GENERAL.—The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), first paragraph:  
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 8 and 13 are rejected under 35 U.S.C. 112(a) or 35 U.S.C. 112 (pre-AIA), first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor or a joint inventor, or for pre-AIA the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 8 requires a longitudinal notch in combination with a carrier and a sharp, and at least functionally, an inserter as well. However, the longitudinal notch is disclosed as 6866 for receiving an inserter

component and there does not appear to be any other carrier-like structure movably supporting sharp 6840. Claim 13 requires a plurality of cantilever members. This limitation cannot be found in the originally filed disclosure.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 6-8 and 10-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ethelfield (US 2008/0009805).

**Regarding claim 6**, Ethelfield disclose an apparatus for inserting a medical device through the skin of a subject, which comprises: a housing (810) including a cantilever member (840); a sharp (880) moveable within the housing from a retracted position to a partially exposed position (Figures 14A-14B).

Ethelfield fails to disclose a sensor as claimed for the Figure 14 embodiment. Ethelfield suggests that the sensor devices or infusion devices of the invention may be used with the same actuation device (paragraphs 0028 and 0063).

It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to have used the sensor 760/761 in place of the infusion device 860/870 in order to combine the advantages of the Figure 14 actuation unit and the sensor of Figure 13.

With this combination the apparatus would further comprise: an electrochemical sensor 760/761 (paragraphs 0018 and 0019) releasably coupled to the sharp for movement with the sharp (paragraph 0091), and for subsequent insertion in the skin of a subject; and a carrier (housing at 850 in Figure 14C) for moveably supporting the sharp (Figure 14B) within the housing; wherein the cantilever member resiliently contacts the carrier (Figure 14B).

**Regarding claim 7**, the housing comprises a distal opening (opening above 850 in Figure 14C) for release of the electrochemical sensor therefrom.

**Regarding claim 8**, the housing defines a longitudinal notch for reception of a drive member of an inserter (in Figure 14A see notch holding portion at end of cantilever which can be considered as a drive member; no drive member is structurally claimed).

**Regarding claim 10**, the housing defines one or more longitudinal ridges (at 810 in Figure 14C) for aligning one of the sharp and the sensor.

**Regarding claim 11**, Ethelfield discloses an apparatus for inserting a sensor comprising: a housing (810) including a cantilever member (840); a medical device

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