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Peter Forsell C/O Implantica Patent Ltd. Ideon Science Park Lund, 22370 SWEDEN			BAYS, PAMELA M	
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**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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## DETAILED ACTION

### *Notice of Pre-AIA or AIA Status*

1. The present application is being examined under the pre-AIA first to invent provisions.

### *Continued Examination Under 37 CFR 1.114*

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 28 November 2023 has been entered.

3. This Office Action is responsive to the amendment filed with the RCE filed on 28 November 2023. As directed by the amendment: Claim 17 has been amended, Claims 1-16, 18-103, 106-109, and 113-116 have been cancelled, and no claims have been added. Claims 119-121, and 124 were previously withdrawn due a Restriction Requirement. Thus, Claims 17, 104, 105, 110-112, 117-118, 122, 123, and 125-126 are presently pending in this application.

### *Claim Rejections - 35 USC § 112*

4. The following is a quotation of the first paragraph 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 the first paragraph of pre-AIA 35 U.S.C. 112:

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.

**5. *Claims 17, 104, 105, 110-112, 117-118, 122, 123, and 125-126 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.***

6. Regarding Claim 17, the claim has been amended to contain 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 applications subject to pre-AIA 35 U.S.C. 112, the inventor(s), at the time the application was filed, had possession of the claimed invention. In Claim 17, the newly added limitations “placing a sensor configured to measure a parameter related to a current state of the energy source” and “measuring a parameter related to a current state of the energy source using the sensor” are not explicitly described in the Specification or Drawings as originally filed, and therefore are considered to be New Matter. In particular, the instant Specification states:

- “the system further comprises a sensor sensing a parameter such as a functional ... said functional parameter is, according to one embodiment, correlated to the transfer of energy for charging an internal energy source implantable in the patient (Paragraph 0471 of Application Publication)

- “the sensor 1025 may be arranged to sense a functional parameter. The functional parameter may be correlated to the transfer of energy for charging an implanted energy source (Paragraph 0685 of Application Publication)

7. However, neither the Specification nor the Drawings explicitly describes, “placing a sensor configured to measure a parameter related to a current state of the energy source” and “measuring a parameter related to a current state of the energy source using the sensor”, and therefore these limitations are considered to be New Matter.

8. For purposes of examination, it is suggested by the Examiner that these limitations be amended to, “placing a sensor configured to measure a functional parameter correlated to the transfer of energy for charging the source of energy” and “measuring a functional parameter correlated to the transfer of energy for charging the source of energy using the sensor” in order to match the language and subject matter as written in the Specification as originally filed.

9. Claims 104, 105, 110-112, 117-118, 122, 123, and 125-126 are rejected for depending on Claim 17.

10. The following is a quotation of 35 U.S.C. 112(b):  
(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**11. *Claims 17, 104, 105, 110-112, 117-118, 122, 123, and 125-126 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being***

***indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor (or for applications subject to pre-AIA 35 U.S.C. 112, the applicant), regards as the invention.***

12. Regarding Claim 17, the claim recites both an “operating device, adapted to operate said heart contacting organ” and “operating an implantable adjustment system”. It is unclear from the claim language as to whether the “operating device” and “an implantable adjustment system” are referring to the same or different elements. Paragraphs 0629-0634 of the Application’s Publication describe both an “operating device” and an “adjustment system” which appear to refer to the same elements/components during use of the device. For purposes of examination, the Examiner will interpret both an “placing an operating device, adapted to operate said heart contacting organ” and “operating an implantable adjustment system” as referring to similar steps/elements. Appropriate correction or clarification is required. Claims 104, 105, 110-112, 117-118, 122, 123, and 125-126 are rejected for depending on Claim 17.

13. Regarding Claim 17, the claim recites, “placing an operating device, adapted to operate said heart contacting organ to periodically exert the external force to the heart contacting organ”. However, it is unclear as to what is particularly meant by “placing” since no particular location of the placement is given. Therefore, this limitation is indefinite. For purposes of examination, the Examiner will interpret this limitation as, “placing an operating device in proximity to the heart, adapted to operate said heart contacting organ to periodically exert the external force to the heart contacting organ”.

Appropriate correction or clarification is required. Claims 104, 105, 110-112, 117-118, 122, 123, and 125-126 are rejected for depending on Claim 17.

14. Regarding Claim 17, the claim has been amended to recite “the energy source” both in Lines 10-11 and in Line 21. However, there is lack of antecedent basis for this limitation in the claim, since the claim previously refers to “a source of energy”.

Therefore, for purposes of examination, the Examiner is interpreting these limitations in Line 10-11 and in Line 21 as “the source of energy”. Appropriate correction or clarification is required. Claims 104, 105, 110-112, 117-118, 122, 123, and 125-126 are rejected for depending on Claim 17.

15. Regarding Claim 17, the claim has been amended to recite “placing a sensor configured to measure a parameter related to a current state of the energy source”. However, it is unclear as to what is particularly meant by “placing” since no particular location of the placement is given. Therefore, this limitation is indefinite. For purposes of examination, the Examiner will interpret this limitation as “placing a sensor configured to measure a parameter related to a current state of the source of energy in proximity to the source of energy”. Appropriate correction or clarification is required. Claims 104, 105, 110-112, 117-118, 122, 123, and 125-126 are rejected for depending on Claim 17.

16. Regarding Claim 17, the claim has been amended to recite “placing a sensor configured to measure a parameter related to a current state of the energy source” and “measuring a parameter related to a current state of the energy source using the sensor”. However, it is unclear and therefore indefinite as to what is intended by the

limitations “a current state of the energy source”, since it is unknown what is meant by “a current state”. These limitations are not explicitly described in the Specification or Drawings as originally filed, and therefore are considered to be New Matter as described above. Therefore, these limitations are indefinite. For purposes of examination, it is suggested by the Examiner that these limitations be amended to, “placing a sensor configured to measure a functional parameter correlated to the transfer of energy for charging the source of energy” and “measuring a functional parameter correlated to the transfer of energy for charging the source of energy using the sensor” in order to provide clarity and to match the language and subject matter as written in the Specification as originally filed. Appropriate correction or clarification is required. Claims 104, 105, 110-112, 117-118, 122, 123, and 125-126 are rejected for depending on Claim 17.

### ***Allowable Subject Matter***

17. Claims 17, 104, 105, 110-112, 117-118, 122, 123, and 125-126 *would be* allowable if rewritten or amended to overcome the rejections under 35 U.S.C. 112(a)/112 (pre-AIA), 1st paragraph and 35 U.S.C. 112(b)/112 (pre-AIA), 2nd paragraph, set forth in this Office action above. **It is noted that the allowable subject matter is based on the claim interpretations and suggested amendments as described in the 35 USC 112 rejection sections above.**



***Response to Arguments***

18. The Examiner agrees with the Applicant's arguments (Page 8 of RCE filed 28 November 2023) that neither the previously cited Shahinpoor (US Publication No. 2003/0032855) nor Evans et al. (US Publication No. 2003/0055410) references discloses or teaches the newly added limitations to independent Claim 17, particularly the additional steps of "placing a sensor configured to measure a parameter related to a current state of the energy source" and "measuring a parameter related to a current state of the energy source using the sensor", in combination with the other method steps of fixating an implantable heart help device as required by independent Claim 17. It is noted that these limitations have been interpreted as described in the 35 USC 112 rejection sections above. Therefore, the previous 35 USC 103(a) rejections as made in the Final Rejection Office Action mailed 28 July 2023 have been withdrawn.

19. The Applicant argues (Pages 7-8 of RCE) that the limitations of Claim 17 are sufficiently clear. However, the Examiner disagrees with these arguments. Claim 17 recites both an "operating device, adapted to operate said heart contacting organ" and "operating an implantable adjustment system". It is unclear from the claim language as to whether the "operating device" and "an implantable adjustment system" are referring to the same or different elements. Paragraphs 0629-0634 of the Applicant's Publication describe both an "operating device" and an "adjustment system" which appear to refer to the same elements/components during use of the device. For purposes of examination, the Examiner will interpret both an "placing an operating device, adapted to operate said heart contacting organ" and "operating an implantable adjustment system" as referring to similar steps/elements. Although the Applicant

specifically argues (Page 8 of RCE), “It is respectfully submitted that the adjustment system could be the same structure as the operating device, as long as it would be capable of performing both claimed functions. Alternatively, it could be two separate devices.”, however, this should be clarified within the claim (e.g., explicitly reciting that they may be a single device or separate devices).

20. Claims 17, 104, 105, 110-112, 117-118, 122, 123, and 125-126 *would be* allowable if rewritten or amended to overcome the rejections under 35 U.S.C. 112(a)/112 (pre-AIA), 1st paragraph and 35 U.S.C. 112(b)/112 (pre-AIA), 2nd paragraph, set forth in this Office action above. **It is noted that the allowable subject matter is based on the claim interpretations and suggested amendments as described in the 35 USC 112 rejection sections above.**

21. It is noted that Claims 119-121, and 124 were previously withdrawn due a previous Restriction Requirement. Claims 119-121, and 124 may be rejoined if/when Claim 17 is allowed, due to their dependency on Claim 17.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAMELA M BAYS whose telephone number is (571)270-7852. The examiner can normally be reached 9:00am - 6:00pm EST.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at <http://www.uspto.gov/interviewpractice>.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jennifer McDonald can be reached on 571-270-3061. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/PAMELA M. BAYS/  
Primary Examiner, Art Unit 3796