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**Datasheet for the decision
of 11 January 2023**

Case Number: T 0393/19 - 3.4.01

Application Number: 12835366.1

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A61B5/113, A61F5/56, A61N1/05,
A61N1/36, A61N1/372

Language of the proceedings: EN

Title of invention:
SYSTEMS AND METHODS FOR DETERMINING A SLEEP DISORDER BASED ON
POSITIONING OF THE TONGUE

Applicant:
Nyxoah SA

Headword:
Sleep disorder / NYXOAH

Relevant legal provisions:
EPC Art. 54, 56, 123(2)

Keyword:
Decision in written proceedings (yes) - announcement of non-
attendance of the oral proceedings



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Case Number: T 0393/19 - 3.4.01

D E C I S I O N
of Technical Board of Appeal 3.4.01
of 11 January 2023

Appellant: Nyxoah SA
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Representative: Patentanwälte Olbricht Buchhold Keulertz
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Decision under appeal: **Decision of the Examining Division of the
European Patent Office posted on 13 September
2018 refusing European patent application No.
12835366.1 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chair P. Scriven
Members: B. Noll
R. Winkelhofer

Summary of Facts and Submissions

- I. The application was refused on the grounds that a main request did not comply with Article 123(2) EPC, auxiliary requests 1 and 2 with Article 54 EPC having regard to D1 (US2011/152965 A1), and auxiliary request 3 with Article 56 EPC having regard to D1 and D2 (WO2008/048471 A2).
- II. The applicant appealed the decision. With the statement of grounds of appeal, the appellant maintained the previous main request and submitted three auxiliary requests. The first and second auxiliary requests are identical to auxiliary requests 1 and 3 underlying the impugned decision.
- III. Claim 1 of the main request reads (reference signs omitted)

*A device, comprising:
an external unit comprising at least one
processor and a primary antenna in
electrical communication with the at least
one processor, wherein the least one
processor is configured to:
receive a physiological signal indicative
of tongue movement in a subject from an
implant unit implanted in the subject
determine whether the tongue movement is
representative of sleep disordered
breathing; and
generate a modulation control signal to*

correct the sleep disordered breathing when the at least one processor determines an occurrence of sleep disordered breathing; characterized in that the at least one processor is further configured to: adjust at least one characteristic of the modulation control signal based on a severity of the sleep disordered breathing, the at least one characteristic of the modulation control signal including voltage amplitude, current amplitude, pulse frequency, or pulse duration.

- IV. Claim 1 of auxiliary request 1 differs from claim 1 of the main request by adding, before "characterized in that",

... and wherein the primary antenna is configured to transmit the modulation control signal to the secondary antenna associated with the implant unit, ...

- V. Claim 1 of auxiliary request 2 differs from that of auxiliary request 1 in that it reads, after "associated with the implant unit":

... and wherein the modulation control signal includes a stimulation control signal configured to interact with the implant unit to cause a contraction in a muscle, characterized in that the at least one processor is further configured to: adjust at least one characteristic of the

modulation control signal based on a severity of the sleep disordered breathing, the at least one characteristic of the modulation control signal including pulse frequency or pulse duration and that the at least one processor is further configured to: generate the sub-modulation control signal for transmission to the implant unit via the primary antenna; detect the movement of the secondary antenna relative to the primary antenna based on a degree of coupling between the primary antenna and the secondary antenna; wherein the degree of coupling includes at least one of a measure of capacitive coupling, radiofrequency coupling, or inductive coupling.

VI. Claim 1 of auxiliary request 3 amends claim 1 of auxiliary request 2 by adding, at the end of the claim,

... and wherein the at least one processor is further configured to re-evaluate the degree of coupling between primary antenna and secondary antenna and select new parameters for the modulation control signal aimed at moving the tongue to a desired location.

VII. The appellant requests that the decision under appeal be set aside and that a patent be granted on the basis of the main request on which the decision is based, or one of auxiliary requests 1 - 3 submitted with the statement of grounds of appeal.

VIII. In preparation for the oral proceedings, the Board issued a communication that explain why, on the basis of a preliminary assessment, none of the requests seemed allowable.

IX. The passages of this communication which are relevant to the decision are as follows:

(...)

Main request

4. In the impugned decision, the definition of the primary antenna in claim 1 was considered as involving added subject-matter.

5. This was because the claim defined the antenna as being in communication with the processor, but omitted its purpose as defined in original claim 6.

6. Including only a part of original claim 6 introduces a generalisation, as the application as filed does not disclose that the first antenna and the modulation control signal can be separate from each other. The antenna is for transmitting the modulation control signal, and an adjustment of a characteristic of the modulation control signal is only disclosed in conjunction with transmitting it via the first antenna. The application does not provide a direct and unambiguous basis for a first antenna without this functional

association with the modulation control signal. For these reasons, the Board concurs with the finding in the impugned decision, point 1 of the reasons, that claim 1 relates to subject-matter extending beyond the content of the application as filed.

7. Further, claim 1 is unclear in defining the first antenna merely as being "in electrical communication with the at least one processor" without any indication of the technical characteristics of this communication. Claim 1 is therefore also not allowable as it does not comply with Article 84 EPC.

Auxiliary request 1

8. Claim 1 of the first auxiliary request was found by the Examining Division to lack novelty having regard to D1.

9. D1 discloses a device for diagnosing the imminent occurrence of obstructive sleep apnea (OSA) and instructing a stimulator to stimulate the tongue muscle to prevent the occurrence. OSA in D1 is understood to be what the application calls "sleep disordered breathing". In detail, the device comprises a reader (150 in figure 2, 450 in Figure 4) for receiving signals from an implant 110, 410 indicating a position or motion of the tongue muscle of a person. The reader comprises a control unit (156,

456), which is a "processor" in the language of the application; and a transceiver (152, 452), which is (or which includes) an antenna to exchange signals with an implant and which is in electrical communication with the control unit. The reader receives a signal indicating the motion of the tongue from an implant unit 100. The signal may indicate the position or distance of the tongue (see D1, paragraphs 38-41). The reader is further configured to determine an OSA from the position or distance of the tongue (paragraphs 42, 43, and 49). An increase of the distance beyond a threshold indicates an OSA event (paragraph 43), and triggers remedial action such as notifying an implanted stimulator 110 to stimulate the tongue muscle (paragraph 54). The skilled person understands this as meaning that the reader generates and transmits a modulation control signal via the transmitter to a secondary antenna in the implant. So far, the disclosure of D1 and the correspondence with features in claim 1 seems to be undisputed.

10. The appellant argues that D1 does not disclose that the device is configured to adjust a characteristic of the modulation control signal based on the severity of "sleep disordered breathing". In the appellant's view, the word adjustment means that a modulation control signal that is already active is modified while remaining active, in dependence of the detected

severity. In the appellant's understanding, this wording could not mean that the modulation control signal was turned on if a "sleep disordered breathing" was detected and was turned off otherwise.

11. The Board does not agree. The feature in question is vague as to the manner of adjustment of the modulation control signal in relation to the "severity" of "sleep disorder breathing". This wording does not exclude that the severity is only discriminated as having one of two states, i.e. above or below a threshold, and that the modulation control signal is set to stimulate or not, as disclosed in D1.

12. For this reason, claim 1 is not distinguished over D1.

13. Even if claim 1 could be understood narrowly, in the sense that a continuous change of the "severity" causes a continuous adaptation of the modulation control signal, it would not involve an inventive step. D1 teaches that, upon the detection of a "sleep disordered breathing" event, a counter-measure is taken, by stimulating the tongue muscle and preventing it from occurring. The skilled person implementing this would have designed the stimulation signal as disclosed in D2 (paragraphs 339-341) such that a "sleep disordered breathing" event is prevented, or disappears if it has already occurred. The skilled person would

have considered adaptively changing the stimulation signal during its application to the stimulator such that the stimulation would successively suppress the sleep disorder breathing event. The application does not provide any specific way of choosing amplitude or time characteristics of the stimulation signal so that the choice is left to the skilled person. The skilled person would have arrived at an appropriate choice of amplitude or pulse sequence characteristics of the stimulation signal in terms of the best outcome for terminating a sleep disorder breathing event by trial and error. Thus, the skilled person would have arrived at the device of claim 1 having regard to D1 in combination with D2.

Auxiliary request 2

14. D1 discloses transmitting a signal from the device to the implant and receiving a response (paragraph 40) and detecting an OSA event on the basis of travel time or signal strength (paragraphs 42 and 45). Thus, D1 discloses a detection based on the "degree of coupling", in the language of claim 1. Further, D1 discloses various ways of coupling, including RFID tags (paragraphs 35, 36), which implies RF coupling. Thus, the additional features in claim 1 do not further distinguish the claimed device from D1. Claim 1 lacks an

inventive step for the reasons given in respect of claim 1 of auxiliary request 1.

Auxiliary request 3

15. The feature of re-evaluating the degree of coupling between primary and secondary antennas and selecting new parameters for the modulation control signal aimed at moving the tongue to a desired location expresses the object of successively preventing or terminating a sleep disorder breathing event by continuously monitoring an appropriate reaction. The feature does not add anything by which the claimed device would be further distinguished from D2, paragraph 340. Therefore, Claim 1 of auxiliary request 3 lacks an inventive step for the same reasons as given for claim 1 of auxiliary request 1 in point 10, above.

X. With a submission submitted shortly before the scheduled hearing date, the appellant indicated that they would not attend the oral proceedings and requested a decision based on the current state of the file.

XI. The Board cancelled the scheduled oral proceedings.

Reasons for the Decision

1. In points 4 to 15 of the communication, cited above, the Board explained why, in its preliminary assessment, none of the requests was allowable.
2. This preliminary assessment was not challenged by the appellant.
3. After further consideration, the Board sees no reason to deviate from its preliminary assessment. The appeal is not allowed, for the reasons given.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chair:



D. Meyfarth

P. Scriven

Decision electronically authenticated