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Datasheet for the decision of 9 September 2020

Case Number: T 1908/15 - 3.2.02

Application Number: 09161958.5

Publication Number: 2116274

IPC: A61B5/00, A61N1/36, A61N1/372, A61N1/05, A61N1/08, A61B5/08

Language of the proceedings: EN

Title of invention:
Obstructive sleep apnea treatment device

Patent Proprietor:
Cyberonics, Inc.

Opponent:
Inspire Medical Systems

Headword:

Relevant legal provisions:
EPC Art. 76(1)

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It can be changed at any time and without notice

Keyword:
Main request - subject-matter extends beyond content of earlier application (yes)
Auxiliary request 1 - prohibition of reformatio in peius (yes)
Auxiliary requests 2 to 4 - subject-matter extends beyond content of earlier application (yes)

Decisions cited:
G 0009/92, G 0004/93, G 0001/99

Catchword:

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Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 1908/15 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 9 September 2020

Appellant: (Opponent)	Inspire Medical Systems 9700 63rd Avenue North, Suite 200 Maple grove, MN 55369 (US)
Representative:	Zimmermann & Partner Patentanwälte mbB Postfach 330 920 80069 München (DE)
Respondent: (Patent Proprietor)	Cyberonics, Inc. 100 Cyberonics Boulevard Houston, TX 77058 (US)
Representative:	Grünecker Patent- und Rechtsanwälte PartG mbB Leopoldstraße 4 80802 München (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 28 July 2015 concerning maintenance of the European Patent No. 2116274 in amended form.**

Composition of the Board:

Chairman	M. Alvazzi Delfrate
Members:	S. Böttcher
	C. Schmidt

Summary of Facts and Submissions

I. The opponent lodged an appeal against the interlocutory decision of the Opposition Division, dispatched on 28 July 2015, that, account being taken of the amendments according to the main request valid at that time, European patent No. EP 2 116 274 and the invention to which it related met the requirements of the EPC.

II. Oral proceedings took place on 9 September 2020.

The appellant (opponent) requested that the decision under appeal be set aside and that the patent be revoked.

The respondent (patent proprietor) requested that the the appeal be dismissed, i.e. that the patent be maintained as confirmed by the contested decision (main request), or on the basis of one of the auxiliary requests 1 to 4, all filed with letter dated 6 August 2020.

III. Claim 1 of the main request reads as follows:

"An implantable medical device, comprising:
an implantable neurostimulator (50) including electronics containing an algorithm;
a stimulation lead (60) having a proximal end connected to the implantable neurostimulator (50) and a distal end connected to a nerve connector (64);
a respiration sensing lead (70) having a proximal end connected to the implantable neurostimulator (50) and a distal portion connected to a respiration sensor (74)

that is configured to detect a respiratory signal; wherein the implantable neurostimulator (50) is configured to trigger the delivery of an electrical signal via the stimulation lead (60) as a function of a fiducial of the respiratory signal detected by the respiratory sensor (74) via the respiration sensing lead (70) and at a fraction of a measured respiratory period after the fiducial is detected, wherein the fiducial corresponds to begin-expiration."

IV. Claim 1 of auxiliary request 1 differs from claim 1 of the main request in that the second part of the claim reads as follows:

"...wherein the implantable neurostimulator (50) is configured to process the respiratory signal detected by the respiration sensor (74) via the respiration sensing lead (70) to measure an expiratory onset and predict future expiratory onsets and time intervals between the predicted expiratory onsets and further configured to trigger the delivery of an electrical signal via the stimulation lead (60) as a function of a fiducial of the respiratory signal and the at least one of the predicted future expiratory onset and the predicted time intervals, wherein the fiducial corresponds to the measured expiratory onset."

V. Claim 1 of auxiliary request 2 differs from claim 1 of the main request in that the second part of the claim reads as follows:

"wherein the implantable neurostimulator (50) is configured to process the respiratory signal detected by the respiration sensor (74) via the respiration sensing lead (70) to measure an expiratory onset and predict future expiratory onsets and time intervals

between the predicted future expiratory onsets and further configured to trigger the delivery of an electrical signal via the stimulation lead (60) as a function of a fiducial of the respiratory signal at a time that is prior to a next predicted expiratory onset by 30% to 50% of the time between subsequently occurring expiratory phases, wherein the fiducial corresponds to the measured expiratory onset."

VI. Claim 1 of auxiliary request 3 differs from claim 1 of auxiliary request 2 in that the following feature has been added to the definition of the trigger time:

"...such that an entire inspiratory phase including a pre-inspiratory phase is captured,"

VII. Claim 1 of auxiliary request 4 differs from claim 1 of auxiliary request 3 in that the following feature has been added to the definition of the pre-inspiratory phase:

"...of 300 ms"

VIII. The arguments of the appellant, as far as relevant for the decision, can be summarised as follows:

Main request - added subject-matter

Claim 140 of the parent application did not form a proper basis for claim 1 of the main request since claim 140 required that stimulation was delivered during inspiration and this feature was missing from claim 1 of the main request.

The feature of triggering stimulation "at a fraction of a measured respiratory period after the fiducial is

detected" did not have a basis in the application as filed and formed added subject-matter. Paragraph [0279], cited by the Opposition Division as support, did not relate to measured time intervals but to predicted time intervals. Also the algorithm described in paragraphs [0241] and [0242] used predicted time intervals instead of measured time intervals. Paragraph [0280], referred to by the Opposition Division in their decision (erroneously as paragraph [0279]), related to a case in which no triggering occurred because a fiducial could not be detected. Hence, this paragraph could not be regarded as a basis for the feature "at a fraction of a measured respiratory period after the fiducial is detected" either.

Claim 1 defined two points in time for the triggering, namely, "as a function of a fiducial of the respiratory signal" and "at a fraction of a measured respiratory period". It could not be derived from the parent application that the algorithm calculated two points in time to trigger the stimulation. Thus, the definition of two points in time in claim 1 also added subject-matter. In any event, there was no disclosure of triggering at a non further specified fraction of the respiratory period.

Auxiliary request 1 - prohibition of reformatio in peius

Claim 1 of auxiliary request 1 did not any more include the feature "at a fraction of a measured respiratory period after the fiducial is detected" which was however present in claim 1 as maintained by the Opposition Division (main request) and defined a feature of the algorithm of the electronics. The deletion of the feature broadened the scope of the

claim and thereby worsened the legal position of the appellant, contrary to the prohibition of reformatio in peius.

Therefore, the request should not be allowed.

Auxiliary request 2 - added subject-matter

Claim 1 of auxiliary request 2 included the feature that the neurostimulator is "configured to process the respiratory signal detected by the respiration sensor (...) to measure an expiratory onset". However, in the application as originally filed it was disclosed that the waveform of the respiratory signal was analyzed to determine peaks which indicate onset of expiratory phases (paragraph [0278]). Hence, to measure an expiratory onset by processing the respiratory signal could not be derived from the original application documents, and therefore this feature included added subject-matter.

The feature "...to process the respiratory signal (...) to (...) predict future expiratory onsets and time intervals between the predicted future expiratory onsets" could not be derived from the original application documents. The algorithm described in paragraph [0279] did not use predicted expiratory onsets (peaks) to predict the time intervals. The start of stimulation was rather calculated by predicting the time intervals between the start of expiration for subsequently occurring respiratory cycles. This could also be derived from paragraphs [0241] and [0242].

IX. The arguments of the respondent, as far as relevant for the decision, can be summarised as follows:

Main request - added subject-matter

The claims of the main request were fully supported by claim 140, Figures 50 and 50A and the description in paragraphs [0046] to [0048] and [0255] to [0288] of the parent application. The fact that claim 140 was a method claim was of no relevance in that context.

The feature of triggering stimulation as a function of a fiducial of the respiratory signal corresponding to begin-expiration and at a fraction of a measured respiratory period after the fiducial is detected could be derived from paragraphs [0277] to [0279] of the description.

Claim 1 of the main request did not define two points in time for the triggering. The term "at a fraction of a measured respiratory period" was to be interpreted in the sense that the stimulation was delivered only for a portion of the respiratory cycle. Thus, this feature related to the duration of the stimulation rather than defining a second point in time for the start of the stimulation. Support for this feature could be found in the first line of paragraph [0277].

Auxiliary request 1 - prohibition of reformatio in peius

If the feature "at a fraction of a measured respiratory period..." was to be interpreted to relate to a further point in time, it could not limit the scope of the claim since it did not define at which fraction of the respiratory period the stimulation was triggered. Hence, the omission of this feature in claim 1 of auxiliary request 1 did not worsen the legal position

of the appellant.

Consequently, the claim did not contravene the principle of no reformatio in peius.

Auxiliary request 2 - added subject-matter

Since the application as originally filed disclosed that the respiratory signal was measured by the respiration sensors, it could also be derived that the expiratory onset was (electronically) measured by processing this signal. The term "to measure" was therefore equivalent to the term "to identify" which was used in a previous auxiliary request and to the term "to detect" which was used in the description of the application. The inclusion of the feature "to process the respiratory signal (...) to measure an expiratory onset" did not add subject matter.

The prediction of future expiratory onsets and time intervals between the predicted future expiratory onsets was disclosed in general terms in paragraphs [0277] to [0279] of the description. The person skilled in the art would understand from these passages that, in order to predict future time intervals, it was necessary to predict the expiratory onsets first. Hence, this feature was also directly and unambiguously derivable from the description.

Reasons for the Decision

1. Subject-matter of the invention

The invention relates to an implantable device for treating obstructive sleep apnea. As illustrated in Figure 2, the device comprises an implantable neurostimulator (INS) 50, a stimulation lead 60 connected to a nerve connector 64, a respiration sensing lead 70 connected to a respiration sensor. In use, an electrical stimulus is delivered by the INS via the stimulation lead to the nerve connector which is connected to the hypoglossal nerve HGN. This nerve innervates a muscle controlling upper airway patency to mitigate the obstruction thereof. The respiratory sensor of the device detects the respiratory cycle. To reduce muscle and nerve fatigue, the stimulus should be delivered only during inspiration, including a brief pre-inspiratory phase of about 300 ms, thus more closely mimicking normal activation of upper airway dilator muscles.

The signal of the respiratory sensor is used to determine the time when the stimulation should start. In particular, the signal is recorded and processed over several breathing cycles, and characteristic data (fiducials) corresponding to specific breathing events are extracted. For instance, a maximum peak in the signal waveform indicates the onset of expiration.

2. Main request - added subject-matter

2.1 The application on which the present patent is based is a divisional application of the European patent application No. 07839472.3 (in the following the "parent application").

The originally filed description of the application underlying the present patent is identical to the description of the parent application. Hence, in order to check the compliance of the claims with Article 76(1) EPC it has to be established whether the subject-matter of the claims can be derived directly and unambiguously from the parent application as originally filed.

2.2 The Board does not concur with the Opposition Division that claim 140 of the parent application can be regarded as a basis for the feature "as a function of a fiducial (...) wherein the fiducial corresponds to begin expiration" in claim 1. According to claim 140, the stimulation is triggered to "occur during inspiration predicted as a function of expiration onset", and this feature has been omitted in claim 1 of the main request.

2.3 Moreover, the feature "and at a fraction of a measured respiratory period after the fiducial is detected" cannot be derived from the parent application. Paragraph [0279] referred to by the respondent discloses that stimulation is started "at the time N that is prior to the next onset of expiration by approximately 30% to 50% of the time between subsequently occurring expiratory phases". Hence, a very specific fraction of the time is mentioned in this paragraph, not just any, and this specific fraction is essential "to capture the entire inspiratory phase" as mentioned in the very same sentence. Moreover, the time is defined as being prior to the next onset of expiration, wherein the next onset of expiration has to be predicted first (paragraph [0279], first sentence).

2.4 The Board does not agree to the respondent's position that the feature "and at a fraction of a measured respiratory period after the fiducial is detected" defines a period for the delivery of the electric signal, as mentioned in the first sentence of paragraph [0277]. The sentence in paragraph [0277] reads "stimulation may be delivered for only a portion of the respiratory cycle", and thus clearly relates to the duration of the stimulation. In contrast, by stating that "the neurostimulator is configured to trigger the delivery of an electrical signal (...) at a fraction of a measured respiratory period" claim 1 explicitly refers to the point of time at which the triggering, i.e. the start, of the stimulation should take place.

2.5 It follows that the main request is not allowable since claim 1 does not meet the requirements of Article 76(1) EPC.

3. Auxiliary requests - admittance

The Board exercised their discretion under Article 13 RPBA to admit the auxiliary requests 1 to 4 filed with letter dated 6 August 2020.

4. Auxiliary request 1 - prohibition of reformatio in peius

The opponent is the sole appellant against the interlocutory decision of the Opposition Division concerning maintenance of the patent in amended form. As ruled in G 9/92 and G 4/93 (see point 2 of the Order, and Reasons, points 15 and 16), under these circumstances the patent proprietor is primarily restricted during the appeal proceedings to defending his patent in the form in which it was maintained by

the Opposition Division. Exceptions to this principle, usually referred to as prohibition of reformatio in peius, are listed in decision G 1/99 (Order).

In claim 1 as upheld by the Opposition Division (current main request) the feature "the neurostimulator is configured to trigger the delivery of an electrical signal (...) at a fraction of a measured respiratory period after the fiducial is detected" is comprised, which has been added during the opposition procedure. By contrast, claim 1 of the first auxiliary request does no longer include this feature. Contrary to the respondent, the Board considers that the feature in question restricts the subject-matter of the claim in that it requires the algorithm to calculate a further point in time, namely, "at a fraction of a measured respiratory period", when the stimulation should start. Hence, the omission of this feature broadens the scope of the claim. This results in an improvement of the proprietor's position putting the sole appellant in a worse situation than if he had not appealed, contrary to the principle of prohibition of reformatio in peius.

Since it is undisputed that none of the exceptions to the prohibition of reformatio in peius (as listed in G 1/99) applies, auxiliary request 1 cannot be allowed for this reason.

5. Auxiliary request 2 - added subject-matter

5.1 In claim 1 of auxiliary request 2 the features "...configured to process the respiratory signal (...) to measure an expiratory onset" and "the fiducial corresponds to the measured expiratory onset" have been added. These features are not directly and unambiguously derivable from the parent application as

originally filed. It is rather mentioned in paragraph [0278] of the description that the respiratory waveform is analyzed to determine peaks that indicate onset of the expiratory phases. In paragraph [0237] it is described how the peak detection sub-routine can be applied to the sensed respiratory signal to detect the peaks. The steps performed by this sub-routine are purely mathematical. Hence, it is not disclosed to measure the expiratory onset (maximum peak) in the respiratory signal. It follows that it is also not disclosed that the measured expiratory onset is used as a fiducial to trigger the stimulation.

The Board does not concur with the respondent that detecting or determining a peak in a curve is equivalent to electronically measuring since both is done electronically. The skilled person would not consider the electronic processing of the respiratory signal in a peak detection routine as a measurement of a peak.

5.2 Furthermore, claim 1 of auxiliary request 2 has been amended to include the feature "... to process the respiratory signal (...) to predict future expiratory onsets and time intervals between the predicted future expiratory onsets". This feature also includes added subject-matter since from the original parent application documents it cannot be derived that the algorithm uses predicted expiratory onsets (maximum peaks) to predict future time intervals. In particular, paragraph [0279], where the algorithm used to calculate the start of stimulation is described, mentions that time intervals between the start of expiration for subsequently occurring respiratory cycles are predicted. Although it is mentioned in paragraph [0278], last sentence, that it may be relatively easy

to predict the occurrence of subsequent peaks, it cannot be derived from paragraphs [0277] to [0279] that this is actually done by the algorithm. It can rather be deduced from paragraphs [0241] and [0242], in which the prediction sub-routine is described, that the detected peaks of recent respiratory cycles are used to calculate the average duration of the cycle and that this average duration is used to predict the duration of the next cycle. Hence, the prediction of future expiratory onsets (peaks) on the basis of predicted time intervals is not disclosed in the application as originally filed, and the teaching in paragraphs [0241] and [0242] shows that it is even not necessary to predict the onsets to predict the time interval.

5.3 It follows that the amendments made to claim 1 of auxiliary request 2 do not meet the requirements of Articles 76(1) EPC.

6. Auxiliary requests 3 and 4

Since the features concerning the measured expiratory onset and the predicted future expiratory onsets are also present in claim 1 of auxiliary requests 3 and 4, none of the requests is allowable.

Order

For these reasons it is decided that:

The decision under appeal is set aside.

The patent is revoked.

The Registrar: The Chairman:

D. Hampe M. Alvazzi Delfrate

Decision electronically authenticated