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Datasheet for the decision of 13 October 2010

Case Number: T 0375/08 - 3.4.01

Application Number: 02736349.8

Publication Number: 1389144

IPC: A61N 1/36

Language of the proceedings: EN

Title of invention:
Heartburn and reflux disease treatment apparatus

Applicant:
Refluxica AG

Opponent:
-

Headword:
-

Relevant legal provisions:
EPC Art. 123(2)

Relevant legal provisions (EPC 1973):
-

Keyword:
-

Decisions cited:
T 0860/93, G 0001/93

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0375/08 - 3.4.01

D E C I S I O N
of the Technical Board of Appeal 3.4.01
of 13 October 2010

Appellant: Refluxica AG
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Representative: Klunker . Schmitt-Nilson . Hirsch
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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 13 November 2007 refusing European patent application No. 02736349.8 pursuant to Article 97(1) EPC 1973.**

Composition of the Board:

Chairman: B. Schachenmann
Members: G. Assi
P. Fontenay

Summary of Facts and Submissions

I. The European patent application No. 02736349.8 (European publication No. 1 389 144; International publication No. WO-A-02/100481) was refused by the examining division.

In its decision, dispatched on 13 November 2007, the examining division held that the subject-matter of claim 1 then on file lacked novelty (Article 54(1),(2) EPC 1973) with regard to the following document:

(D1) EP-A-1 004 330.

II. The applicant (appellant) lodged an appeal, received on 10 January 2008, against the decision to refuse the application. On the same day, the fee for the appeal was paid and the statement setting out the grounds of appeal was received.

III. Oral proceedings took place on 13 October 2010.

IV. The appellant requested that the decision under appeal be set aside and a patent be granted on the basis of the following documents:

Main request:
Claim 1 as filed with a letter of 8 September 2010,
Claims 2-95 as filed with a letter of 21 June 2007,
Description pages 2, 14, 15 as filed with the letter of 21 June 2007,
Description pages 1, 3-13, 16-22 of the application as published (under the PCT),
Drawing sheets 1/4-4/4 of the application as published;

First auxiliary request:
Claim 1 as filed with the letter of 8 September 2010,
Claims 2-93 as filed with the notice of appeal,
Description pages as for the main request,
Drawing sheets as for the main request;

Second auxiliary request:
Claim 1 as filed with the letter of 8 September 2010,
Claims 2-92 as filed with the notice of appeal,
Description pages as for the main request,
Drawing sheets as for the main request.

V. The wording of claim 1 of the main request reads as follows:

"*An apparatus for treating a patient who suffers from heart burn and reflux disease, comprising an implantable stimulation device (4; 56) adapted to engage with the patient's cardia sphincter (58) and a control device (6, 10; 40; 62, 64) for controlling the stimulation device to stimulate the cardia sphincter with energy pulses to increase the sphincter tonus, so that the cardia completely closes, said control device being operable by the patient in that the apparatus can be set out of operation, wherein the control device (6, 10; 40; 62, 64) is further operable by the patient to set the apparatus (4; 56) into operation, in which operational state the stimulation device continuously alternates at a time when the patient does not swallow between an operation mode, in which the cardia sphincter is stimulated with said energy pulses, and a rest mode, in which the cardia sphincter is not stimulated.*"

The wording of claim 1 of the first auxiliary request reads as follows:

"*An apparatus for treating a patient who suffers from heart burn and reflux disease, comprising an implantable stimulation device (4; 56) adapted to engage with the patient's cardia sphincter (58) and a control device (6, 10; 40; 62, 64) for controlling the stimulation device to stimulate the cardia sphincter with energy pulses to increase the sphincter tonus, so that the cardia completely closes, said control device being operable by the patient in that the apparatus can be set out of operation, wherein the control device (6, 10; 40; 62, 64) is further operable by the patient to set the apparatus into operation, in which operational state the stimulation device (4; 56) continuously alternates between an operation mode, in which the cardia sphincter is stimulated with said energy pulses, and a rest mode, in which the cardia sphincter is not stimulated, wherein the apparatus further comprises at least one implantable sensor for sensing at least one physical parameter of the patient, wherein the control device is adapted to control the stimulation device to cease the continuous alternation between the operation mode and the rest mode and to put the stimulation device in the rest mode in response to the sensor sensing the physical parameter of the patient.*"

The wording of claim 1 of the second auxiliary request reads as follows:

"*An apparatus for treating a patient who suffers from heart burn and reflux disease, comprising an*

implantable stimulation device (4; 56) adapted to engage with the patient's cardia sphincter (58) and a control device (6, 10; 40; 62, 64) for controlling the stimulation device to stimulate the cardia sphincter with energy pulses to increase the sphincter tonus, so that the cardia completely closes, said control device being operable by the patient in that the apparatus can be set out of operation, wherein the control device (6, 10; 40; 62, 64) is further operable by the patient to set the apparatus into operation, in which operational state the stimulation device (4; 56) continuously alternates between an operation mode, in which the cardia sphincter is stimulated with said energy pulses, and a rest mode, in which the cardia sphincter is not stimulated, wherein the apparatus further comprises at least one implantable sensor for sensing as a physical parameter of the patient at least the contraction wave in the esophagus caused by the patient swallowing food, wherein the control device is adapted to control the stimulation device to cease the continuous alternation between the operation mode and the rest mode and to put the stimulation device in the rest mode in response to the sensor sensing the contraction wave in the patient's esophagus."

The remaining claims according to all the requests are dependent claims.

VI. The revised version of the European Patent Convention or EPC 2000 entered into force on 13 December 2007. In the present decision, reference is made to "*EPC 1973*" or "*EPC*" for EPC 2000 (EPC, Citation practice, pages 4-6) depending on the version to be applied according to Article 7(1) of the Revision Act dated 29 November 2000

(Special Edition No. 1 OJ EPO 2007, 196) and the decisions of the Administrative Council dated 28 June 2001 (Special Edition No. 1 OJ EPO 2007, 197) and 7 December 2006 (Special Edition No. 1 OJ EPO 2007, 89).

Reasons for the Decision

1. The appeal is admissible.

2. Article 123(2) EPC

2.1 Claim 1 of the published application (hereafter application as filed) includes the following functional features characterising a control device for controlling a stimulation device to stimulate a cardia sphincter:

"*... the control device is operable by the patient to control the stimulation device to continuously alternate between an operation mode, in which the cardia sphincter is stimulated with energy pulses, and a rest mode, in which the cardia sphincter is not stimulated.*"

2.2 Claim 1 according to the main request includes the following amended functional features, the reference signs being omitted:

"*... said control device being operable by the patient in that the apparatus can be set out of operation, wherein the control device is further operable by the patient to set the apparatus into operation, in which operational state the stimulation device continuously*

alternates at a time when the patient does not swallow between an operation mode, in which the cardia sphincter is stimulated with said energy pulses, and a rest mode, in which the cardia sphincter is not stimulated".

The amended functional features mentioned above are also recited by claims 1 according to the first auxiliary request and the second auxiliary request, but without the expression "*at a time when the patient does not swallow*".

2.3 The question arises as to whether the amendments mentioned above introduce subject-matter which extends beyond the content of the application as filed (Article 123(2) EPC). When dealing with this question, the issue may be left undecided as regards the allowability of the amendment that the "*apparatus*", rather than the "*stimulation device*", is set out of operation and into operation. In the appellant's view (letter of 8 September 2009, page 1), such an amendment represented a clarification rendering claim 1 of all the requests more in line with the disclosure of the application as filed (page 3, lines 8-10).

2.4 The description of the application as filed (page 2) indicates document D1 as a background art which can be regarded as useful for understanding the invention (Rule 27(1)(b) EPC 1973). According to page 2, lines 9-20 of the application as filed, D1 discloses "*a system for treating gastroesophageal reflux by continuously stimulating the lower esophageal sphincter of a patient with stimulus pulses, such as a continuous train of electric pulses, in order to maintain the sphincter in*

a substantially closed state. There are a motility sensor attached to the patient's esophagus to sense esophageal motility, such as the patient swallowing, and inhibiting means to temporarily inhibit the stimulation in response to signals from the sensor. However, the patient has no control of the system and the sphincter is continuously stimulated, except when esophageal motility occurs, which may result in decreased stimulation effect in the long run." It is not essential for the present discussion whether this summary correctly reproduces the disclosure of D1.

Starting from the disclosure of D1 as cited above, the object of the present invention consists in providing "*a new convenient heartburn and reflux disease treatment apparatus, the performance of which may be affected by the patient at any time after operation, in particular when various needs arise over the day, so that the patient always is satisfied*" (page 2, lines 22-26).

This object is achieved by the provision of a heartburn and reflux disease treatment apparatus of the kind stated initially on page 1, lines 4-10 of the application as filed, i.e. comprising an implantable electric stimulation device and a control device, characterised in that "*the control device is operable by the patient to control the stimulation device to continuously alternate between an operation mode, in which the cardia sphincter is stimulated with energy pulses, and a rest mode, in which the cardia sphincter is not stimulated*" (application as filed, page 2, line 27 to page 3, line 1 and claim 1).

2.5 The interpretation of the statement on page 2, line 27 to page 3, line 1, in particular, which is crucial for the assessment under Article 123(2) EPC, should be derived by having regard to its context in the application as filed (T 860/93 (OJ 1995, 047), Reasons, point 5.1, "*Ex praecedentibus et consequentibus optima fit interpretatio*").

It results from the foregoing that the context is given by the summary of the disclosure of D1, as literally mentioned above, in the light of which the object of the present invention is defined. An essential issue consists in that, according to the disclosure of D1 as indicated above, the patient has no control of the known system and the sphincter is continuously stimulated, except when esophageal motility occurs, which may result in decreased stimulation effect in the long run. These disadvantages, i.e. the lack of control by the patient and the decrease in the stimulation effect, lead to the definition of the object underlying the present invention, which essentially consists in the provision a treatment apparatus, the performance of which may be affected by the patient at any time. According to the application as filed, this object is achieved by a treatment apparatus, in which:

(a) the control device is operable by the patient,
(b) to control the stimulation device,
(c) to continuously alternate between an operation mode, in which the cardia sphincter is stimulated with energy pulses, and a rest mode, in which the cardia sphincter is not stimulated.

In other words, the treatment apparatus according to the application as filed allows the patient to operate on the control device (feature (a)) with the intention of controlling the stimulation device (feature (b)), the result being a continuous alternation of the stimulation device between an operation mode and a rest mode (feature (c)). It should be noted that the sentence bridging pages 2 and 3 of the application as filed does not give any detailed information about the way in which the stimulation with energy pulses should take place.

As already stated above, the treatment system of D1, according to the presentation on page 2 of the application as filed, relies on a continuous stimulation with a train of electric pulses, if the inhibiting effect of the mobility sensor is neglected. A skilled person, when reading the mentioned disclosure on pages 2 and 3 of the application as filed, would thus understand that the technical contribution of the treatment apparatus of the present invention (application as filed, sentence bridging pages 2 and 3) over the treatment system known from D1 only consists in the implementation of a control by the patient leading to a continuous alternation between an operation mode with stimulation and a rest mode without stimulation. No indication can be found that the operation mode would itself consist of distinct phases. Indeed, the application as filed does not disclose, either explicitly or implicitly, any specific sequence of energy pulses. In particular, it does not disclose a sequence as claimed, i.e. a sequence during the operational state, in which the stimulation device continuously alternates between an "*operation mode, in*

which the cardia sphincter is stimulated with said energy pulses [in plural]*, and a rest mode, in which the cardia sphincter is not stimulated*". Therefore, the application as filed does not disclose the example of sequence shown on the attachment A filed with the appeal, in which the "*operation mode*" consists of three pulses.

It should be noted that the Board's understanding mentioned above is consistent with the advantages recited on page 3 of the application as filed. Due to the alternation between an operation mode with stimulation and a rest mode without stimulation under the control by the patient, the energy consumption will be lower as compared with the continuous stimulation system of D1. Moreover, during a rest mode, the cardia sphincter can recover. In this respect, the application as filed does not provide any information concerning recovery requirements like, for example, the minimum time duration needed for achieving an effect. Last, since the control device is operable by the patient, he or she may choose when the apparatus should be in operation depending on the circumstances and needs.

2.6 The appellant, however, submitted that the disclosure discussed above should be understood in another way. The sentence bridging pages 2 and 3 of the application as filed included the following elements:

(a) the control device,
(b) is operable by the patient,
(c) to control the stimulation device,
(d) to continuously alternate between an operation mode and a rest mode.

For a correct understanding, the sentence should be read in its context, in particular page 2, line 22 to page 3, line 14 of the application as filed. Moreover, the elements of the sentence should be related to each other in an appropriate way, i.e. according to the sequence (b)-(a)-(c)-(d). The patient thus operated on the control device depending on the needs arising over the day (page 2, lines 22-26). The control device was then responsible for controlling the stimulation device which itself provided for the continuous alternation between an operation mode and a rest mode. In other words, the basic structure of the sentence was "*X operated on Y to control Z in doing something*", wherein X was the patient, Y the control device and Z the stimulation device, the intended activity being the continuous alternation. It resulted from this understanding that, with regard to the claimed wording, the control device was operable by the patient to set the apparatus (or the stimulation device) out of operation and into operation depending on the needs that might arise (application as filed, page 2, lines 22-26). In each operational state, the stimulation device continuously alternated between an operation mode, in which the cardia sphincter was stimulated with said energy pulses, and a rest mode, in which the cardia sphincter was not stimulated (application as filed, sentence bridging pages 2 and 3). In claim 1 of the main request, the addition "*at a time when the patient does not swallow*" should be regarded as a simple clarification for avoiding the objection of lack of novelty raised by the examining division against claim 1 then on file with regard to D1.

In the Board's view, the appellant's interpretation is indeed possible. However, it is not more cogent than the Board's understanding as mentioned above.

2.7 With regard to the function of Article 123(2) EPC, the Enlarged Board of Appeal held in G 1/93 (OJ 8/1994, 541) that "*the underlying idea is clearly that an applicant shall not be allowed to improve his position by adding subject-matter not disclosed in the application as filed, which would give him an unwarranted advantage and could be damaging to the legal security of third parties relying on the content of the original application*" (Reasons, point 9).

This idea found application in the jurisprudence of the boards of appeal, according to which an amendment should be regarded as introducing subject-matter which extends beyond the content of the application as filed, if the overall change in the content of the application results in the skilled person being presented with information which is not directly and unambiguously derivable from that previously presented by the application as filed, taking account of matter which is implicit to a person skilled in the art.

2.8 In the present case, the amendment "*... said control device being operable by the patient in that the apparatus can be set out of operation, wherein the control device is further operable by the patient to set the apparatus into operation, in which operational state the stimulation device continuously alternates between an operation mode, in which the cardia sphincter is stimulated with said energy pulses, and a rest mode, in which the cardia sphincter is not*

stimulated" is not directly derivable from the disclosure of the application as filed. Rather, the relevant passages of the original disclosure, as discussed above, support two technical meaningful interpretations mutually excluding each other, one of which, the Board's one, results in the conclusion that the amendments introduce new subject-matter. Under these circumstances, the requirement that any amendment shall be unambiguously derivable from the application as filed is not met either.

2.9 It follows from the foregoing that claims 1 of all the requests on file have been amended in such a way that they contain subject-matter which extends beyond the content of the application as filed. Hence, none of the requests is allowable.

Order

For these reasons, it is decided that:

The appeal is dismissed.

The Registrar The Chairman:

R. Schumacher B. Schachenmann