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**Datasheet for the decision  
of 19 September 2018**

**Case Number:** T 2441/16 - 3.4.01

**Application Number:** 09733481.7

**Publication Number:** 2280758

**IPC:** A61N1/36

**Language of the proceedings:** EN

**Title of invention:**  
PSYCHIATRIC DISORDER THERAPY CONTROL

**Applicant:**  
Medtronic, Inc.

**Headword:**  
Therapy Control / MEDTRONIC

**Relevant legal provisions:**

EPC Art. 56  
EPC R. 103(1)(a)

**Keyword:**

Inventive step - main request (no) - auxiliary request (no)  
Reimbursement of appeal fee - (no)

**Decisions cited:**

J 0007/83



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Case Number: T 2441/16 - 3.4.01

**D E C I S I O N**  
**of Technical Board of Appeal 3.4.01**  
**of 19 September 2018**

**Appellant:** Medtronic, Inc.  
(Applicant) 710 Medtronic Parkway NE  
Minneapolis, MN 55342-5604 (US)

**Representative:** Dehns  
St. Brides House  
10 Salisbury Square  
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**Decision under appeal:** **Decision of the Examining Division of the  
European Patent Office posted on 6 June 2016  
refusing European patent application No.  
09733481.7 pursuant to Article 97(2) EPC.**

**Composition of the Board:**

**Chairman** P. Scriven  
**Members:** T. Zinke  
D. Rogers

## Summary of Facts and Submissions

- I. The Examining Division refused European patent application No. 09 733 481.7.
- II. The decision reads (emphasis as in the original):

*In the communication(s) dated **23.05.2016** the applicant was informed that the application does not meet the requirements of the European Patent Convention. The applicant was also informed of the reasons therein.*

*The applicant filed no comments or amendments in reply to the latest communication but requested a decision according to the state of the file by a letter received in due time on **23.05.2016**.*

***The European patent application is therefore refused on the basis of Article 97(2) EPC.***

In the cited communication dated 23 May 2016, the Examining Division held that claim 1 of both pending requests lacked novelty (Art. 54(1) and (2) EPC) over document D3 (US-A-2005/0081847) and lacked an inventive step starting from document D7 (WO-A-2007/050780) as closest prior art and taking into account the common knowledge. Evidence for the common knowledge was given by documents D9 (US-A-2007/173901), D10 (WO-A-2006/063558) and D11 (WO-A-2003/035165) introduced into the examination proceedings with the cited communication.

III. The appellant (applicant) filed an appeal against the decision.

In the notice of appeal, the appellant stated:

*It is not clear whether an Appeal has to be filed in this case. The Examiner issued an Examination Report dated 2 May 2016 [sic] giving a response deadline of 2 October 2016. Before that deadline though, and with no indication that the deadline no longer applied, a decision issued, requiring an appeal. This appears to be an irregularity and we ask for a refund of the Appeal fee if, as the Examination Report suggests, the application can be continued in writing. If this is not an option, this Notice of Appeal should stand.*

With the statement of grounds, the appellant requested that the decision under appeal be set aside and that the application be allowed to proceed to grant on the basis of sets of claims of a main request or an auxiliary request, both filed with the statement of grounds, but which were the same as the requests pending before the Examining Division. Further, the appellant provided arguments with regard to novelty and inventive step for the independent claims of both requests.

In the alternative, oral proceedings were requested.

IV. In a first communication pursuant to Art. 15(1) RPBA, the Board informed the appellant that it was not clear whether or not reimbursement of the appeal fee due to a substantial procedural violation was requested.

- V. In reply, the appellant essentially repeated the statement cited above from the notice of appeal without providing further details.
- VI. In a second communication under Art. 15(1) RPBA, sent with the summons to oral proceedings, the Board provided:
- Its preliminary interpretation of the claim wording.
  - Its preliminary view that neither the main nor the auxiliary request was allowable, due to lack of novelty and lack of inventive step.
  - A detailed analysis of the documents exchanged between the Examining Division and the appellant between 19 and 23 May 2016, as apparent from the electronic file.
  - Its preliminary opinion that, according to this analysis, there seemed to be no substantial procedural violation but rather an administrative error.
- VII. The appellant did not respond in substance to that second communication, but
- Indicated that it would not be represented at oral proceedings.
  - Withdrew its request for oral proceedings.
  - Requested a decision based on the state of the file.
- VIII. Oral proceedings took place as scheduled, in the absence of the appellant.
- IX. Independent claim 1 of the main request reads:
- A system comprising:  
means for delivering psychiatric disorder  
therapy to a patient according to a therapy  
program; and  
means (26) for sensing a physiological*

*parameter of the patient in response to the psychiatric disorder therapy, wherein the physiological parameter comprises at least one of a respiratory rate, electrodermal activity, thermal activity or muscle activity;*  
*characterized by*  
*means (70) for determining whether the patient is in a positive mood state or a negative mood state based on the sensed physiological parameter; and*  
*means for controlling the means for delivering the psychiatric disorder therapy based on the determined patient mood state, wherein the means for controlling controls the means for delivering to stop the delivery of the psychiatric disorder therapy in response to a determination, by the means for determining, that the patient is in a positive mood state, and*  
*wherein the means for sensing generates a signal indicative of the physiological parameter and the means for determining the patient mood state at least one of compares a peak amplitude of the signal to a threshold amplitude, compares an average amplitude of the signal to the threshold amplitude, compares a median amplitude of the signal to the threshold amplitude, compares a trend in a waveform of the signal over time to a template, compares a power level within one or more frequency bands of the signal to a threshold power level, or compares a ratio of power levels in two or more frequency bands of the signal to a threshold power level ratio, and determines*

*the patient mood state based on the comparison.*

- X. Independent claim 1 of the auxiliary request adds, after *characterized by*:

*means for storing a plurality of mood states and associated physiological parameter characteristics, the physiological parameter characteristics comprising a threshold amplitude, a template of a physiological signal, a threshold power level, or a threshold power level ratio, and the plurality of mood states comprising a positive mood state and a negative mood state ....*

## **Reasons for the Decision**

*Main request*

1. *Inventive step*
- 1.1 The Board agrees with the Examining Division with regard to lack of inventive step starting from document D7 as closest prior art (cf. communication of 23 May 2016, section 3.2.1).
- 1.2 In particular, D7 relates explicitly to determining a mood state (e.g page 15, lines 2 to 7, *depression, happiness, sadness, fear, anxiety, etc.*) by sensing physiological or neurological responses, as for example

heart rate or galvanic skin response (page 18, lines 5 to 7, page 19, lines 3 and 26 to 28), and controlling and modifying the therapy based on the sensed signal (see e.g. Figure 3 and page 13, lines 20 to 22).

- 1.2.1 The argument provided by the appellant in the grounds of appeal that "*D7 neither teaches nor suggests any particular adjustment of the stimulation parameters and, therefore, there is no suggestion of the means for controlling as required by current claim 1*" (page 2, sixth paragraph) is not persuasive.

Figures 3 and 4 of D7 show a feedback loop from a "*stimulation control processing element 24*" to a "*neurologic stimulator 20*", and this feedback loop is, for instance, explicitly stated on page 13, lines 15 to 22 to "*thus allow modification of the stimulation provided to the subject 12*".

Also, original claims 11 to 13 of D7 clearly describe a method for varying the stimulation as a result of changes in the neurological state.

- 1.2.2 The Board further notes that the current wording of independent claim 1 includes several "*means for ...*" features. Such features are interpreted as meaning "*means suitable for*" and not necessarily "*means adapted to*", the latter being possibly narrower.

In this particular application, it is the Board's understanding that (for instance) *means for delivering psychiatric disorder therapy* only defines the general suitability for delivering electrical pulses or chemical compositions to the brain, as in the prior art. Also, *means for determining whether the patient is in a positive mood state or a negative mood state based*



*on the sensed physiological parameter* encompasses prior art processors that evaluate measured signals in order to decide whether a pathology exists or not.

- 1.2.3 In the grounds of appeal, the appellant argued that a difference over the cited prior art was established by the different physiological parameters that were analysed, by the different algorithms that were used in order to determine psychiatric disorders based on the parameters and by different therapies that were delivered.

In this regard, the Board notes that, indeed, particular reference is made to psychiatric disorders throughout the description, however, there seems to be no particular disclosure about how the measured parameters, the determination algorithms and the delivered therapy are particularly adapted for psychiatric disorders and how they distinguish themselves from other brain-stimulation approaches.

- 1.2.4 The appellant stated, further, that *The person skilled in the art would understand that the determination of the patient's mood state from the sensed physiological parameter requires the parameter to be a parameter that is understood in the art as being indicative of mood state and not any parameter of any signal* (page 2, first paragraph).

Taking into account that the specification of the present application does not disclose any particular differences in the parameters, in the determination algorithm, or in the delivered therapy, either these differences are not disclosed in sufficient detail (which would result in an objection under Article 83 EPC) or they were well known to the skilled person (and

so would not provide an inventive step (Article 56 EPC)).

1.3 Hence, "modifying" the stimulation is known from D7. The skilled person knows that stopping therapy is an option when the patient's mood is positive. That is a matter of common general knowledge. But it is, in any case, known from documents D9 (Fig. 5, paragraph [0028]), D10 (abstract and page 35, lines 7-15) and D11 (page 4, line 14 to page 6, line 10) that "stopping" of a therapy might be an option, when the patient no longer experiences psychiatric symptoms. Hence it is obvious to "modify" the stimulation so that it is stopped by stopping it.

1.4 Consequently, claim 1 of the main request lacks an inventive step (Article 56 EPC).

#### *Auxiliary request*

2. Inventive step

2.1 The additional feature *means for storing a plurality of mood states and associated physiological parameter characteristics* does not qualify as a further distinguishing feature as compared to D7.

2.2 D7 discloses a *neurologic response index* (page 14, lines 1 to 10) as a

*form of medical algorithm expert system using methods such as look-up tables, decision matrices, etc, to supplement and speed up data processing. It may be used to support the selection of appropriate*

*evidence based medical therapies based on the available data representing specific neurologic states. In one aspect of the invention, the neurologic response index may be utilized to specify the type and form of neurologic stimulation ...*

This "*neurologic response index*" is a means for storing a plurality of mood states and associated physiological parameter characteristics as claimed. Further, as discussed above, the suitability for storing mood states correlated to physiological parameters does not differ from the suitability for storing other brain states correlated to physiological parameters.

2.3 Hence, claim 1 of the auxiliary request also lacks an inventive step.

3. *Substantial procedural violation*

3.1 It is unclear whether reimbursement of the appeal fee has been requested (see points VI and VII), but the Board will assume that it has.

3.2 According to Rule 103(1)(a) EPC, the appeal fee is reimbursed where the Board deems an appeal to allowable, if such reimbursement would be equitable by reason of a substantial procedural violation.

3.3 The Board will consider below whether or not the Examining Division committed a substantial procedural violation in its handling of this case.

3.4 In order to determine whether a substantial procedural violation took place, the Board has checked the

electronic file in order to ascertain the course of events in these proceedings, in particular between 19 and 23 May 2016.

- 3.5 It appears to the Board that the Examining Division made an error in its decision by referring to a communication dated 23 May 2016, rather than to a fax of 19 May 2016. In the Board's view, this error was an administrative one that does not qualify as a substantial procedural violation. According to J 7/83 *Interruption procédure* OJ 1984, 211, a substantial procedural violation is an objective deficiency affecting the entire proceedings.

According to the Board's understanding, however, the appellant was aware of the Examining Division's objections with regard to the then pending main and auxiliary requests, as confirmed by the email correspondence between the examiner and the representative on the morning of 23 May 2016. At 08:29, the Examiner asked whether the comments of the Examining Division to the latest amendments and arguments had been received and whether the representative's client had instructed her to attend the oral proceedings of 26 May 2016. At 09:41, the representative responded that she would not attend the oral proceedings and that a letter withdrawing the request for oral proceedings and requesting a decision on the file would be sent later that day. The representative also thanked the Examining Division for *your previous detailed comments*. This appears to be a reference to detailed comments that were received prior to that date via the fax of 19 May 2016.

Hence, when withdrawing the request for oral proceedings and requesting a decision based on the

state of the file, the appellant was aware that the most probable outcome was a refusal. In addition, with these requests the appellant voluntarily and unconditionally refrained from making further comments or amendments during the examination proceedings.

- 3.6 That the appellant, for some days between the actual receipt of the communication dated 23 May 2016 and the receipt of the decision to refuse, might have believed that the proceedings could possibly continue in writing, does not qualify as *effecting the entire proceedings*, since the appellant had already accepted that a refusal might result from its former behaviour.

## Order

### For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



R. Schumacher

P. Scriven

Decision electronically authenticated