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**Datasheet for the decision
of 20 June 2024**

Case Number: T 1443/21 - 3.4.01

Application Number: 13170859.6

Publication Number: 2810691

IPC: A61N1/36, G06F19/00

Language of the proceedings: EN

Title of invention:

A system for planning and/or providing a therapy for neural applications

Applicant:

Medtronic Bakken Research Center B.V.

Headword:

Simulating and steering deep brain stimulation / Medtronic

Relevant legal provisions:

EPC Art. 83, 84, 123(2)

EPC R. 103(4) (c)

RPBA 2020 Art. 11

Keyword:

Amendments - main request- allowable (no)

Remittal - special reasons for remittal (no)

Claims - main request, auxiliary request - clarity (no)

Sufficiency of disclosure - (no)



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Case Number: T 1443/21 - 3.4.01

D E C I S I O N
of Technical Board of Appeal 3.4.01
of 20 June 2024

Appellant: Medtronic Bakken Research Center B.V.
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Decision under appeal: **Decision of the Examining Division of the
European Patent Office posted on 19 February
2021 refusing European patent application No.
13170859.6 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chair P. Scriven
Members: A. Medeiros Gaspar
D. Rogers

Summary of Facts and Submissions

- I. The applicant appealed the Examining Division's decision to refuse the application.

- II. The Examining Division found claim 1 of the sole request before them to contravene Article 123(2) EPC.

- III. On appeal, the appellant requested:
 - that the decision be set aside and a patent granted on the basis of the same request (main request), or
 - that the case be remitted to the examining division "for any outstanding issues not dealt with by the decision" to be addressed, should the refusal on the grounds of Article 123(2) EPC be found unjustified; or
 - that a patent be granted on the basis of an auxiliary request submitted with the grounds of appeal.

- IV. Oral proceedings were also requested, if the Board were minded to uphold the decision.

- V. In a communication sent with a summons to oral proceedings, the Board set out its preliminary opinion (Articles 15(1) and 17(2) RPBA 2020). It included:
 - a negative view on the question of added matter having regard to the main request,
 - an explanation as to why the Board was not minded to remit the case to the Examining Division for

- further prosecution, irrespectively of whether or not the condition for that request was met; and
- a negative opinion with regard to clarity and sufficiency of disclosure for the subject-matter defined in claim 1 of the main and the auxiliary requests.

VI. More than one month after notification of this communication, the appellant withdrew the request for oral proceedings, and requested a decision "based on the state of the file".

VII. The oral proceedings were cancelled.

VIII. Claim 1 of the main request reads (reference signs omitted):

*A system for planning and providing a therapy for neurostimulation applications comprising a lead having one or more electrodes configured to stimulate a volume of tissue of a patient, the system comprising:
processing means configured to combine specific anatomical data and/or functional data and information about the volume of tissue, TV, of the patient that can be stimulated by the lead with a stimulation field F;
at least one steering and field shaping means configured to steer the therapy delivered by the lead depending on an output of the processing means;*

visualisation means configured to depict the volume of tissue of the patent to be stimulated by the lead; and simulation means configured to provide feed-forward simulation of the shape of the volume of tissue, TV, that will be stimulated by the lead; wherein the visualisation means is configured to combine patient images with fed-forward images.

IX. Claim 1 of the auxiliary request reads (modifications with regard to the main request indicated):

*A system for planning and providing a therapy for neurostimulation applications comprising a deep brain stimulation, DBS, lead having ~~one or more~~ a complex array of electrodes configured to stimulate a volume of tissue of a patient, the system comprising:
processing means configured to combine specific anatomical data and/or functional data and information about the volume of tissue, TV, of the patient that can be ~~stimulated~~ influenced by the lead with a stimulation field F;
at least one steering and field shaping means configured ~~to steer~~ such that the therapy delivered by the lead can be steered depending on an output of the processing means;
visualisation means configured to depict the volume of tissue of the patent to be ~~stimulated~~ addressed by the lead; and*

simulation means configured to provide feed-forward simulation of the shape of the volume of tissue, TV, that will be stimulated provided by the lead; wherein the visualisation means is configured ~~to combine such that~~ patient images with feed-forward images.

- X. The relevant sections of the communication under Article 15(1) RPBA read as follows

Context of the invention, as described in the application

4. The invention relates, inter alia, to neurostimulation systems, in particular, to deep brain stimulation (DBS) systems.

5. According to the description, precise control of the spatial distribution of the stimulation field in relation to the brain anatomy is important, so as to maximize the therapeutic benefits of the deep brain stimulation while avoiding unwanted side-effects.

6. One proposal is to simulate the electrical fields generated by a lead, so as to identify the set of stimulation parameters that is able to generate an electrical field of a shape that matches the shape of the volume of tissue to be stimulated.

Main request - Article 123(2) EPC

7. Claim 1 of the main request is directed to *a system for planning and providing therapy for neurostimulation applications*. It defines a system comprising features defined in original claims 1, 2, 4, 6, and 9, but with some modifications.

8. The Examining Division concluded that there was no basis, in the original disclosure, for the replacement of the definition of the system as comprising *at least one therapy delivery means* by the definition of the system as comprising *a lead having one or more electrodes*.

9. While there is basis in original application (e.g. claim 4) for the replacement of *at least one therapy delivery means* by *a lead*, there is no literal basis for the lead *having one or more electrodes*.

10. The appellant refers to paragraphs [0019] and [0020] of the publication of the original application, as well as to original claims 1, 4, and 5, as providing basis for this amendment.

11. However, original claim 4, as well as paragraph [0019], merely refer to a lead for neurostimulation, while claim 5 clearly defines the lead as comprising a plurality of electrodes, among other limitations.

12 It is true that paragraph [0020] discloses that the lead *may* comprise a plurality of electrodes, but it is also true that the invention relies on the possibility of shaping the stimulation field generated by a neurostimulation lead, which can only be achieved with leads comprising a plurality of electrodes (paragraph [0027]).

13. The skilled person would, then, not directly and unambiguously deduce from the term "may" employed in paragraph [0020] that a lead comprising a single electrode is encompassed by the teaching of the present application.

14. As claim 1 of the main request encompasses systems comprising leads with only one electrode, it extends beyond the content of the original application.

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19. Therefore claim 1 of the main request contravenes Article 123(2) EPC.

...

Request for remittal

24. The appellant requests that the case be remitted to the Examining Division "for any outstanding issues not dealt with by the decision to be addressed", should the decision to refuse the application on the grounds of Article 123(2) EPC be found "not justified".

25. However, irrespectively of whether or not the condition of this request is met, no special reasons justify remittal (Article 11 RPBA 2020), whether on the basis of the main request or of the auxiliary request.

26. It is noted that, already in the search opinion established for this application, objections were raised under Articles 54 and 56 EPC, in view of D1; as well as under Article 84 EPC. Also, during examination, objections under Articles 84 and 123(2) EPC were raised against previously-submitted amended set of claims, and the communication sent with the summons to oral proceedings before the Examining Division indicated that novelty and inventive step might also be discussed.

27. Hence, even if the issues under Articles 54, 56, and 84 EPC were not dealt with in the contested decision, they are not new to the applicant, who dealt with them during examination.

28. In fact, if a grant of a patent is to ordered, as the appellant has requested, the Board would need to be persuaded that all those previously raised issues were also overcome and that all conditions for the grant of the patent are met.

Article 84 EPC (and Article 83 EPC)

29. Claim 1 of both requests is unclear.

30. The claim defines, for instance, *steering and field shaping means configured such that the therapy delivered by the lead is steered, or can be steered, depending on the output of the processing means.*

31. Such definition amounts to a definition of a desired result, and neither specifies how it is to be achieved, nor even how the therapy delivered by the lead is to be "steered", depending on the output of the processing means (Article 84 EPC).

32. The same applies to the definition of *simulation means configured to provide feed-forward simulation of the shape of the volume of the tissue to be stimulated, that will be provided by the lead.* The claim neither defines the data on the basis of which simulation is effected, nor how, such simulation is to be implemented, quite apart from the fact that the term *feed-forward simulation* is itself not clear (Article 84 EPC).

33. Also, the disclosure of the rest of the application seems insufficient for the skilled person to implement either the simulation or the steering defined in the claim (Article 83 EPC).

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37. Therefore claim 1 of both the main request and the auxiliary request contravenes

Articles 84 and 83 EPC.

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Reasons for the Decision

1. The preliminary opinion expressed and explained the Board's view that the subject-matter of claim 1 of the main request contravened Article 123(2) EPC (points 7 to 14); that the Board saw no justification for a remittal of the case to the Examining Division for further prosecution (points 24 to 28); and that claim 1 of the main request and the auxiliary request contravened Articles 83 and 84 EPC (points 29 to 33).
2. The appellant has not commented on, let alone contested, this preliminary opinion.
3. After further consideration, the Board does not see any reason to depart from its preliminary opinion.
4. Therefore, for the reasons indicated, neither the main request nor the auxiliary request is allowable; nor does the Board allow the request for remittal.
5. In the absence of an allowable request, the appeal has to be dismissed.

No partial reimbursement of the appeal fee

6. Since the withdrawal of the request for oral proceedings was filed more than one month after notification of the Board's communication under Article 15(1) RPBA, the appellant is not entitled to a partial reimbursement of the appeal fee under Rule 103(4)(c) EPC.

Order

For these reasons it is decided that:

The appeal is dismissed

The Registrar:

The Chair:



D. Meyfarth

P. Scriven

Decision electronically authenticated