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Datasheet for the decision of 14 March 2023

Case Number: T 2652/17 - 3.4.01

Application Number: 13717084.1

Publication Number: 2841156

IPC: A61N1/375

Language of the proceedings: EN

Title of invention:
TRIAL STIMULATION SYSTEMS

Applicant:
Medtronic, Inc.

Headword:
Trial Stimulation System / Medtronic

Relevant legal provisions:
EPC Art. 84, 56
RPBA Art. 12(4)
RPBA 2020 Art. 13(1)

Keyword:
Claims - clarity - auxiliary requests 1 to 7 (no)
Inventive step - auxiliary requests 1 to 7 (no)
Late-filed request - main request withdrawn before the Examining Division
Amendment to appeal case - auxiliary requests 1A to 7A - suitability of amendment to resolving issues raised (no)

Decisions cited:
T 2057/12, T 0826/94, T 0570/91

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Case Number: T 2652/17 - 3.4.01

D E C I S I O N
of Technical Board of Appeal 3.4.01
of 14 March 2023

Appellant: (Applicant)	Medtronic, Inc. 710 Medtronic Parkway NE Minneapolis, Minnesota 55432 (US)
Representative:	Zimmermann & Partner Patentanwälte mbB Postfach 330 920 80069 München (DE)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 19 June 2017 refusing European patent application No. 13717084.1 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chair	P. Scriven
Members:	T. Zinke
	R. Winkelhofer

Summary of Facts and Submissions

I. The Examining Division refused the application for lack of inventive step in the light of documents D1 (US-A-5 374 279) and D2 (US-A-2010/106204). This applied to all then pending requests, i.e. the main request and auxiliary requests 1 to 6.

II. The applicant appealed that decision.

III. In the statement of grounds of appeal, the appellant filed sets of claims for a main and for seven auxiliary requests 1 to 7; and requested that the decision under appeal be set aside and amended such that a patent be granted on the basis of one of them. The main request is identical to the claims as originally filed, save for the inclusion of reference signs. Auxiliary requests 1 to 7 are identical to the main request and auxiliary requests 1 to 6, respectively, underlying the appealed decision. With the notice of appeal, the appellant also requested reimbursement of the appeal fee.

IV. The Board arranged oral proceedings. In a communication under Article 15(1) RPBA, the appellant was informed of the Board's preliminary opinion on the main issues at stake.

V. In reply, the appellant filed further auxiliary requests 1A to 7A, and webpage print-outs ZP1 to ZP5

dated 7 March 2023, in order to support their argumentation with regard to inventive step:

- ZP1: https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/treating-pain-with-spinal-cord-stimulators
- ZP2: https://flexikon.doccheck.com/de/Spinal_Cord_Stimulation
- ZP3: https://www.spine-health.com/treatment/pain-management/spinal-cord-stimulation-trial-period
- ZP4: https://www.bostonscientific.com/en-US/products/spinal-cord-stimulator-systems/scs_lead_portfolio.html
- ZP5: https://www.neuromodulation.abbott/us/en/chronic-pain/getting-neurostimulation/trying-neurostimulator.html

VI. At oral proceedings, the appellant withdrew the request for reimbursement of the appeal fee.

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

A disposable trial electrical stimulator (102, 200) comprising:
a therapy delivery module (208) configured to deliver electrical stimulation via at least one stimulation lead (106A, 106B, 216) connected to the trial stimulator; and
a lead coupler (122) configured to connect the at least one stimulation lead directly to the trial stimulator, wherein the lead coupler is configured to connect a plurality of types of stimulation leads

directly to the trial stimulator without any intervening lead connection devices; and
a processor (204) configured to control the therapy delivery module to deliver the electrical stimulation via the at least one stimulation lead,
wherein the trial stimulator is sterilized.

VIII. Claim 1 of auxiliary request 1 is amended, as compared to claim 1 of the main request, by adding, at the end:

... [sterilized], wherein the trial stimulator is configured to automatically detect the type of stimulation lead connected to the trial stimulator.

IX. Claim 1 of auxiliary request 2 is amended as compared to claim 1 of auxiliary request 1 by adding, at the end:

...[trial stimulator], and wherein the processor is configured to automatically, and without user interaction, cause the therapy delivery module to cease delivery of stimulation when the at least one stimulation lead is disconnected from the trial stimulator.

X. Claim 1 of auxiliary request 3 is amended as compared to claim 1 of auxiliary request 1 by adding after the last feature:

... [trial stimulator], and wherein the trial stimulator is configured to automatically limit at least one of a number of stimulation programming options available via a programmer, limit or select one or more stimulation values, or select different programs according to which the trial stimulator can deliver stimulation via stimulation lead based on the type of lead detected.

XI. Claim 1 of auxiliary request 4 is amended as compared to claim 1 of auxiliary request 1 by amending the feature defining the lead coupler, so that it reads (with emphasized amendment):

... a lead coupler (122) configured to connect the at least one stimulation lead directly to the trial stimulator, wherein the lead coupler is integral with the trial stimulator and is configured to connect a plurality of types of stimulation leads directly to the trial stimulator without any intervening lead connection devices; ...

XII. Claim 1 of auxiliary request 5 is amended as compared to claim 1 of auxiliary request 1 by adding, at the end:

...[trial stimulator], and wherein the trial stimulator is not hermetically sealed.

XIII. Claim 1 of auxiliary request 6 combines the amendments of auxiliary requests 1, 2, 3, and 4.

XIV. Claim 1 of auxiliary request 7 combines the amendments of auxiliary requests 1, 2, 3, and 5.

XV. Independent claims 1 of auxiliary requests 1A to 7A are amended, as compared to respective claims 1 of auxiliary requests 1 to 7, by not claiming a disposable trial electrical stimulator, but instead

> *A system (100) comprising:*
> *an external programmer (108);*
> *at least one implantable stimulation lead (106); and a disposable trial electrical stimulator [...]*

as defined in claim 1 of the respective auxiliary request 1 to 7; and by adding, to the definition of the therapy delivery module (amendments emphasized):

> *... a therapy delivery module (208) configured to deliver electrical stimulation via <u>one or more electrodes of</u> ~~at~~ <u>the</u> least one stimulation lead (106A, 106B, 216) connected to the trial stimulator; ...*

Reasons for the Decision

Main Request - Consideration

1. The claims for the main request are identical to those of the application as originally filed, except that added reference signs have been inserted. The claims were amended during the examination proceedings; the appellant thus did not pursue the originally-filed claims during examination.

2. It is established case law that the Boards of Appeal do not admit requests that were withdrawn during first instance proceedings, i.e. not maintained (Case Law of the Boards of Appeal, Tenth Edition, 2022, V.A.5.11.4 c) with references), under Article 12(4) RPBA 2007, which applies here (see Article 25(2) RPBA 2020).

3. Thus, there is no reason to take this claim set into account and the Board declines to do so.

Auxiliary request 1 - Clarity

4. The subject matter of claim 1 of auxiliary request 1 is defined by reference to a "plurality of types of stimulation leads". The lead coupler, as part of the disposable trial electrical stimulator, is defined as *being configured to connect a plurality of types of stimulation leads directly to the trial stimulator without any intervening lead connection devices* and, further, the trial stimulator is *configured to automatically detect the type of stimulation lead connected to the trial stimulator*.

5. However, neither the stimulation leads themselves, nor any plurality of types of stimulation lead, are part of the claimed trial electrical stimulator. Neither is there any definition what actually might be intended or what should be understood by "type" of a stimulation lead.

6. Classification of stimulation leads into different "types" is possible in many ways, e.g. by geometrical dimensions, connectors, electrical characteristics, number and form of electrodes on the lead, intended treatments, intended placements in the human body, materials, etc. It is even possible that only identical stimulation leads are considered being of the same "type". Due to the near endless possibilities for classifying stimulation leads into different types, a definition of what constitutes a type would be necessary to define the claimed subject-matter in a clear way (Article 84 EPC). Otherwise, the concept of detecting possible types is too vague and leaves open too many possibilities (e.g. optical inspection, electrical measurements, geometric restrictions), for which no basis can be found in the specification.

7. The specification only gives embodiments for detecting a type of a stimulation lead by electrical measurements (A1 publication, page 14, line 29 to page 15, line 27; page 22, line 4 to page 23, line 2; page 34, lines 5 to 31), and this might suggest that leads are classified according to (say) their resistance. In these embodiments, the detected type is used, for instance, to limit the number of stimulation programming options. This, however, is not the only type of stimulation lead in the application. In Figures 4a and 4b, and the corresponding description (page 38, line 21 to page 39, line 8) it is disclosed that the lead coupler may

include differently formed slots to receive different types of stimulation lead. This embodiment apparently defines different types not by electrical differences, but by geometrical differences. For these geometrical differences, however, no automatic detection of the different types is mentioned. Since the automatic detection is not foreseen for these different "types", it is not clear whether different geometrically characterized types should be encompassed by the term "a plurality of types" or not. These passages from the description show that "type", without further specification, is an unclear concept.

8. A second clarity issue in claim 1 is the definition of the lead coupler as being configured to connect a plurality of types of stimulation lead directly to the trial stimulator *without any intervening lead connection device*. First, this definition is contradictory in itself, because the lead coupler is such an "intervening lead connection device" and, thus, with such a lead coupler defined in the claim, there is no "without any intervening lead connection device". Second, since the stimulation leads are neither defined in the claim nor part of the claimed trial stimulator, it is not clear how "without any intervening lead connection device" can be a feature of the latter. Such "intervening lead connection device" might be understood as being a part of the stimulation lead itself.

9. The appellant referred to Figures 4a and 4b and the corresponding specification (A1 publication, page 38, line 12 to page 39, line 12) and explained that the intention was to define that the lead coupler provided the adaptor functionality (with the different slots for different lead ends shown in Fig. 4A), so that

different types (apparently geometrically distinguished) of lead were connected directly to the lead coupler. In that way it was distinguished from an indirect connection between the stimulation leads and the trial stimulator via an adaptor (as in Fig.1, "adaptor 26").

10. This is not persuasive. Since neither the leads, nor any possible adaptor, are defined in the claim, the contradictory function of the lead coupler as an intervening lead connection device - which should not be present - remains; i.e. the intended meaning is not apparent in the claim.

11. To conclude, for auxiliary request 1, the requirement of clarity (Article 84 EPC) is not fulfilled.

Auxiliary request 1 - Inventive Step

12. Notwithstanding the lack of clarity, the subject-matter of claim 1 also lacks inventive step with regard to a combination of documents D1 and D2, even if - in the appellant's favour - a restricted interpretation of the unclear features is used for this assessment. As is suggested by the specification, the different types of the stimulation leads are interpreted as meaning different electrode configurations on the lead in order to use different stimulating programs for different treatments (A1 publication, page 14, line 29 to page 15, line 27; page 22, line 4 to page 23, line 2; page 34, lines 5 to 31). The lead coupler is an "intervening lead connection device" for connecting these different types of stimulation lead to the trial stimulator.

13. In the decision under appeal, the Examining Division interpreted claim 1 of the then pending main request, which is identical to claim 1 of auxiliary request 1 on appeal in the way just set out. It held that its subject-matter differed from the disclosure of D1 *only in that the trial stimulator is configured to automatically detect the type of stimulation lead connected to the trial stimulator*. The Examining Division formulated the problem to be solved as increasing safety for the patient and held that the claimed solution did not involve an inventive step because it was suggested by document D2 (decision, reasons, section II.I).

14. The appellant objected to this analysis and provided three lines of counter-arguments:

(a) The skilled person would not combine documents D1 and D2, since they did not relate to the same technical field. D1 related to cardiac stimulation, whereas D2 related to other sorts of stimulation, in particular for the treatment of pain syndromes and movement disorders (statement of grounds, section 1.3.2).

(b) Document D1 did not disclose a "trial" stimulator that is "disposable", but rather an implantable stimulator instead. This also implied that the skilled person would not start from document D1, because it referred to different subject-matter (statement of grounds, section 1.1)

(c) The additional feature that the trial stimulator is configured automatically to detect the type of stimulation lead connected to the trial stimulator was not disclosed in document D2, contrary to the Examining Division's argument (statement of grounds, section 2).

15. The Board does not agree.

16. With regard to argument a), the skilled person would consult document D2 because documents D1 and D2 relate to technical fields that are closely related. Whereas D1 deals with cardiac stimulation and D2 with spinal cord stimulation, there is an overlap of the technical fields. It might be that a skilled person in cardiac stimulation might not know exactly about treatment parameters for spinal cord stimulation. However, general mechanical or electrical aspects that are not directly related to treatment - such as connecting options for leads to a stimulator - are among the overlapping part of these technical fields. Both technical fields have to solve the same issue of somehow connecting leads - which should be very similar in these fields - to an electrical stimulator.

17. With regard to argument b) that the Examining Division's analysis with regard to inventive step was wrong, because it started from document D1, which did not qualify as "closest prior art", two aspects need to be addressed, one of a general nature, the other relating to the present case.

18. On the more general note, the appellant argued that a "closest prior art document" should be identified, and this - after an inventive step starting from this particular ("closest") document had been established - precluded any possibility of a successful inventive step attack starting from a different prior art document. This is not in line with the Boards' case law (see, for instance, even for documents from different technical fields T 2057/12 (reasons 3.2.2)). There must be an inventive step, that is, the invention must not have been obvious, starting from every possible

starting point. The idea of introducing a "closest prior art document" only helps in shortening the discussion, when it is clear that starting from other prior art could not challenge the result, because it is evidently far less obvious to arrive at the claimed invention. This might be because of missing features, technical area, etc.

19. With regard to the present application, the Board concurs with the Examining Division, that the terms "disposable" and "trial" do not help in distinguishing the claimed device from a "non-disposable" or "non-trial" device. Claim 1 defines no feature that is proper to devices that are "disposable" or those that are for "trial". These terms, rather, reflect the intention of the manufacturer or supplier or medical practitioner. They do not reflect any inherent property of the stimulator itself. It might be uneconomic to use a particular stimulator for a trial and then dispose of it, but that is not a technical issue. For inventive step, it is only technical differences that count.

20. In addition, D1 explicitly refers to the use of the device disclosed for trial purposes (D1, column 5, lines 8 to 12):

> *The device can thus be safely be handled with a subcutaneous electrode being used for pre-implant screening and testing, without endangering the physician or other medical personnel during delivery of defibrillation shocks.*

21. Hence, document D1 discloses a device of the same type as the present application and is a promising starting point for evaluating inventive step, contrary to the

situations in T 826/94 (see reasons 3.1) and T 570/91 (see reasons 5), cited by the appellant.

22. Documents ZP1 to ZP5 were provided by the appellant in an attempt to show that the skilled person would know that implantable pulse generators and trial stimulators were different devices. However, while these documents show that, before implanting a pulse generator, a trial phase over several days with an external stimulator is generally foreseen, there is no indication that the implanted pulse generators are any different from the external pulse generators used in the trial phase. In particular, there is no evidence that any difference between these generators is implied by the terms "implantable pulse generator" and "trial stimulator" alone and without any further technical feature that might distinguish them.

23. The appellant also argued that these devices could be distinguished due to the different surroundings and the different phases of the implantation process, in which they were used. For instance, an implantable pulse generator was hermetically sealed, which was not necessary for an external, trial stimulator; and external trial stimulators included a user interface (A1 publication, Fig. 5, "user interface 212"; page 31, line 13 to page 32, line 23) and possibly a button to cease stimulation (A1-publication, Figure 4a, "button 124"; page 23, lines 15 to 20), which an implantable pulse generator had not.

24. There is no evidence, however, that the term "trial stimulator" excludes an "electrical stimulator used for trial (or testing) purposes" as in D1. And any features distinguishing a trial stimulator - as apparently been

understood by the appellant - from an implantable pulse generator are lacking in the claim.

25. With regard to argument c) that D2 allegedly did not disclose the distinguishing feature, the Board is not persuaded. D2 discloses in paragraph [0047]

> *In at least some embodiments, the connection monitoring system may also be able to distinguish between different types of trial system cables (e.g., a trial system cable with one proximal end and sixteen conductors for electrically coupling with sixteen electrodes on a connected lead, or a trial system cable with two proximal ends and eight conductors on each proximal end, each conductor coupling with eight electrodes on a connected lead), or one or more other accessory devices, such as a test load box, connector box, or the like.*

and in paragraph [0070]

> *In at least some embodiments, the connection monitoring system may also be used to distinguish the type of device disposed in one or more ports of the external trial system.*

26. Further, at the end of paragraph [0071] it is even disclosed that resistance or impedance measurements are used to determine types of trial system cables:

> *In at least some embodiments, the one or more types of accessory devices each*

include at least one interface contact for electrically coupling with the external trial system 1002. Accordingly, the non-overlapping impedance ranges may be used to distinguish between different types of trial system cables and other devices which may be disposed in the external trial system 1002.

27. Consequently, even with the interpretation of the claimed subject-matter proposed by the appellant, auxiliary request 1 is not allowable, because it lacks an inventive step.

Auxiliary request 1A

28. Auxiliary request 1A was submitted in response to the Board's preliminary opinion. Its consideration is at the discretion of the Board (Article 13(1) RPBA). The Board must exercise its discretion in view of, inter alia, whether the party has demonstrated that the amendments made, prima facie, overcome the issues raised by the Board.

29. The amendments made are not related to the lack of clarity or to the lack of inventive step objections against claim 1 of auxiliary request 1. Hence, they are prima facie not suited to overcoming these objections. In particular, they do not define the "types of stimulation leads" in any further detail. Claiming a system including an external programmer, a stimulation lead and a trial stimulator still lacks inventive step, since these components and, thus, a corresponding system, are disclosed in document D2 (see, for

instance, Fig.11, "programming unit 1108", "electrodes 134").

30. Hence, auxiliary request 1A is not considered (Article 13(1) RPBA).

Auxiliary requests 2 to 7

31. None of the amendments made in auxiliary requests 2 to 7 affects the "types of stimulation leads" or "without any intervening lead connection device", and none of them overcomes the lack of clarity objection raised against claim 1 of auxiliary request 1.

32. In particular, the amendment made to auxiliary request 3 is not suited to overcoming the lack of clarity objections against claim 1 of auxiliary request 1. It limits the actions of the trial stimulator in response to a detected type, but this does not define the types themselves or make the meaning clear.

33. In addition, they do not overcome the lack of inventive step of claim 1 of auxiliary request 1.

34. In particular, with regard to auxiliary request 2 the appellant argued that D2 only disclosed an indicator for a loss of connectivity, but not that the stimulation automatically ceased in that case.

35. This, however, is not correct. Document D2 explicitly discloses in [0055]:

> *In at least some embodiments, when a loss of electrical connectivity is detected, the*

external trial system may automatically turn off.

36. With regard to the additional feature in claim 1 of auxiliary request 3 that the trial stimulator somehow reacts to the type of the stimulation lead detected, the Board concurs with the Examining Division that (decision, last sentence of section II.3):

Adapting, e.g. limiting, the therapeutic options to the type of therapy applicator (e.g. stimulation lead) which has been connected to the therapeutic generator (e. g. stimulator) is an obvious standard measure to increase patient's safety which is well-known in the field of electro-therapy.

37. The appellant did not provide any counter-argument, in appeal proceedings, with regard to the Examining Division's position.

38. With regard to inventive step of claim 1 of auxiliary request 4, the appellant argued (statement of grounds, section 5), that neither D1 nor D2 disclosed a lead coupler that was integral with the trial stimulator.

39. However, document D1, in Figure 5 (see connector housing 30 and device housing 32), discloses the same arrangement of lead coupler and trial stimulator as the present application (for instance in Figures 2A, 2B, 2C), between trial stimulator 16 and coupler 32. The present application does not define "integral" any further. Hence, the term "integral" seems to mean nothing more than that both parts are somehow arranged closely together, which is shown in D1.

40. With regard to inventive step of claim 1 of auxiliary request 5, the Board concurs with the Examining Division that a hermetic seal for a trial simulator is not necessary and, thus, not hermetically sealing it would have been obvious to the skilled person (decision, section II.5).

41. With regard to inventive step of claim 1 of auxiliary request 6, no particular effect can be identified as being due the combination of the amendments of auxiliary requests 1, 2, 3, and 4, so that the lack of inventive step objections against the features alone as discussed above equally apply.

42. With regard to inventive step of claim 1 of auxiliary request 7, no particular effect can be identified as being due the combination of the amendments of auxiliary requests 1, 2, 3, and 5, so that the lack of inventive step objections against the features alone as discussed above equally apply.

Auxiliary requests 2A to 7A

43. The amendments to auxiliary requests 2A to 7A as compared to respective auxiliary requests 2 to 7 are the same as the amendments made to auxiliary request 1A as compared to auxiliary request 1. Prima facie, as stated above, these amendments do not overcome the clarity objections against the respective auxiliary requests 2 to 7.

44. For that reason, auxiliary requests 2A to 7A are not considered (Article 13(1) RPBA).

Conclusion

45. Since the main request is not considered; auxiliary requests 1 to 7 lack clarity and lack inventive step; and auxiliary requests 1A to 7A are not considered, the appeal has to be dismissed.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chair:

D. Meyfarth P. Scriven

Decision electronically authenticated