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**Datasheet for the decision
of 13 November 2019**

Case Number: T 0094/14 - 3.4.01

Application Number: 08726632.6

Publication Number: 2125100

IPC: A61N1/00

Language of the proceedings: EN

Title of invention:

MUSCLE STIMULATOR

Applicant:

Mainstay Medical Limited

Headword:

Muscle Stimulator / Mainstay Medical

Relevant legal provisions:

EPC Art. 123(2), 84, 83, 54

Keyword:

Amendments - allowable (yes)
Claims - clarity (yes)
Sufficiency of disclosure - (yes)
Novelty - (yes)



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Case Number: T 0094/14 - 3.4.01

D E C I S I O N
of Technical Board of Appeal 3.4.01
of 13 November 2019

Appellant: Mainstay Medical Limited
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Swords, Dublin (IE)

Representative: Vossius & Partner
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Decision under appeal: **Decision of the Examining Division of the
European Patent Office posted on 26 June 2013
refusing European patent application No.
08726632.6 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman P. Scriven
Members: T. Zinke
J. Geschwind

Summary of Facts and Submissions

- I. The Examining Division refused European patent application 08 726 632.6 for lack of clarity and lack of novelty in the light of documents D1 (US-A-2001/053885) and D2 (WO-A-2006/133444).
- II. The applicant appealed the decision.
- III. With the statement setting out the grounds of appeal, the appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of one of six sets of claims, resubmitted but identical to the requests (main and first to fifth auxiliary requests) before the Examining Division. As an "auxiliary measure", oral proceedings were requested.
- IV. The Board arranged to hold oral proceedings. In a communication under Article 15(1) RPBA, the appellant was informed of the Board's preliminary opinion. In particular, the Board agreed with the position of the Examining Division that the claims of the main request and of the first to fifth auxiliary request lacked clarity (Article 84 EPC). Depending on the interpretation of the claims, the Board also set out possible further objections, for instance, lack of novelty (Article 54 EPC) as compared to documents D1 and D2.
- V. In reply, the appellant filed claims for a new, sixth auxiliary request. The main and first to fifth auxiliary requests were maintained. In addition, the appellant provided arguments with regard to the issues raised against the main and first to fifth auxiliary

requests and argued for bases in the original application for the new sixth auxiliary request.

VI. During oral proceedings, the appellant filed a new main request and withdrew all auxiliary requests.

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

A neuromuscular electrical stimulation system comprising a lead system having electrodes coupled to an implantable, programmable pulse generator (10, 20, 22), and a fixation anchor suitable for anchoring to boney structure of a vertebra, characterized in that said lead system having electrodes is configured to be implanted in or adjacent to tissue associated with local segmental control of the lumbar spine, and said pulse generator (10, 20, 22) is programmed with a pulse frequency, magnitude and duration to deliver electrical stimulation to said electrodes to induce contraction of the multifidus and thereby improve muscle strength, or endurance of the multifidus to alleviate pain.

Reasons for the Decision

Main request - Amendments (Article 123(2) EPC)

1. The Board is satisfied that the amendments made to claim 1 of the main request comply with Article 123(2) EPC.
2. In particular, the amendment introducing a "lead system" is based, for instance, on original page 11, lines 3 to 5; the last full paragraph on page 11 and the first four lines of the paragraph bridging pages 11 and 12, and page 13, second full paragraph.
3. The amendment introducing "a fixation anchor suitable for anchoring to boney structure of a vertebra" is based on page 13, second full paragraph in combination with the wording used on page 11, penultimate line.
4. The amended wording "to deliver electrical stimulation to said electrodes to induce contraction of the multifidus" (emphasis by the Board) is based on, for instance, claims 1 and 2 as originally filed.
5. The amended wording "and thereby improve muscle strength, or endurance of the multifidus to alleviate pain" is based on original page 9, first full paragraph in combination with the paragraph bridging pages 12 and 13.
6. The combination of the features is based on original figure 2 and the corresponding specification on page 11, last three lines to page 13, first two lines. Whereas these passages deal with "stimulation" of a muscle instead of inducing its contraction, it is evident for a skilled person from the entire

specification that "stimulation" primarily means "induce contraction" of a muscle. This is also clear from claim 1 as originally filed, which uses the wording "sufficient to cause at least one muscle of the local spine stabilization system to contract" and from original claim 2, which specifies that said muscle is the multifidus.

7. Other amendments to the claims of the main request only remove alternatives or cancel dependent claims, so that the amended subject-matter does not extend beyond the content of the application as originally filed.

Main request - Clarity (Article 84 EPC)

8. A major issue discussed during examination proceedings, addressed by the Board in its communication under Article 15(1) RPBA and discussed at oral proceedings was the definition of the claimed pulse parameters. Throughout the examination proceedings, and with the claim sets as filed with the statement setting out the grounds of appeal, the pulse parameters were defined by the desired effect, namely "to restore the muscle function" (or "to restore muscle strength, endurance or motor control"). However, in none of the claims pending prior to oral proceedings, was there any definition of an initial muscle function (or muscle strength, endurance or motor control) to which the - apparently degraded - muscle function should be "restored". This left any limit to the pulse parameters entirely open, since it seemed possible to define a restored muscle function for any pulse parameter whatsoever.
9. On the other hand, it was undisputed that programmable, implantable pulse generators were known at the time the

invention was made, so that any invention should lie in the chosen pulse parameters.

10. Further, a large number of possible target muscles were initially considered for application of the pulses, which made it even more obscure which pulse parameters were actually claimed.
11. With the amended claim wording of the main request, the wording "restore muscle function" (or "restore muscle strength, endurance of motor control") as the sole limit to define the pulse parameters has been removed. The amended wording now clearly specifies that the pulse parameters are chosen to induce contraction of the multifidus. With that amendment, it is possible to determine whether the pulse parameters disclosed in the prior art are able to induce that contraction or not.

Main request - Sufficiency of disclosure (Article 83 EPC)

12. There is no reason to consider that a person skilled in the art would not know how to choose pulse parameters that can induce a contraction of the multifidus or how to determine them using simple experiments. Evidence for this understanding can be found in several documents, published before the priority date of the application and filed by the appellant during examinations proceedings :

D4: Keller et al. "Muscular contributions to dynamic dorsoventral lumbar spine stiffness", European Spine Journal, vol. 16(2): pages 245 to 354, February 2007;

D5: Solomonow et al., "The Ligamento-Muscular Stabilizing System of the Spine", *Spine*, Vol. 23 (23), pages 2552 to 2562, December 1998;

D8: Crago et al.: "The Choice of Pulse Duration for Chronic Electrical Stimulation via Surface, Nerve, and Intramuscular Electrodes", *Annals of Biomedical Engineering*, vol. 2 (3), pages 252 to 264 (September 1974);

D9: Mortimer and Bhadra, "Peripheral Nerve and Muscle Stimulation", *Neuroprosthetics: Theory and Practice* (Series on Bioengineering & Biomedical Engineering, Vol. 2), Chapter 4.2, pages 1 to 48, Hoch and Dhillon, Eds., World Scientific Publishing Company, 2005;

D10: Peckham and Knutson, "Functional Electrical Stimulation of Neuromuscular Applications", *Annual Review of Biomedical Engineering*, Eng. 7, pages 327 to 360).

Main request - Further prosecution

13. In the decision under appeal, novelty objections were raised against the then pending independent claims based on documents D1 and D2. Those novelty objections, however, were based in part on the unclear limits of the pulse parameters and interpreted these unclear limits broadly.

14. With the amendments made, it is now clear that the pulse parameters must be chosen to induce muscle contraction of the multifidus. At least the pulse frequency that is necessary for that purpose (e.g. 2.5 to 20 Hz, D4, page 247, left column, lines 6 to 10) is neither disclosed in document D1 (no particular frequency is disclosed in D1 at all) nor in document D2 (only pulse frequencies of 40 Hz and 240 Hz are disclosed in D2:[0150]).

15. Since there is no evidence on file that, for the purposes of electrical pulse applications disclosed in documents D1 and D2 (for instance, spinal cord stimulation (SCS) and peripheral nerve field stimulation (PNFS) D1: [0055], D2: Abstract), frequencies are used that can also be used for inducing muscle contraction of the multifidus, the subject-matter of claim 1 is novel as compared to D1 or D2 (Article 54 EPC).

16. During first instance proceedings, inventive step was not discussed.

17. Hence, the Board remits the case to the first instance for further prosecution, possibly with prior art to be found in a further search.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the Examining Division for further prosecution.

The Registrar:

The Chairman:



D. Meyfarth

P. Scriven

Decision electronically authenticated