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**Datasheet for the decision
of 6 July 2021**

Case Number: T 1631/15 - 3.4.01

Application Number: 02724022.5

Publication Number: 1383572

IPC: A61N1/00, A61N2/02

Language of the proceedings: EN

Title of invention:

APPARATUS AND METHODS FOR DELIVERY OF TRANSCRANIAL MAGNETIC
STIMULATION

Patent Proprietor:

BOARD OF REGENTS, THE UNIVERSITY OF TEXAS SYSTEM

Opponent:

Ruohonen Jarmo

Headword:

Transcranial magnetic stimulation / University of Texas

Relevant legal provisions:

EPC Art. 100(c)
RPBA 2020 Art. 13(2)

Keyword:

Grounds for opposition - added subject-matter - yes (main request) - no (auxiliary request 3)



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Case Number: T 1631/15 - 3.4.01

D E C I S I O N
of Technical Board of Appeal 3.4.01
of 6 July 2021

Appellant: Ruohonen Jarmo
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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 16 May 2015
rejecting the opposition filed against European
patent No. 1383572 pursuant to Article 101(2)
EPC.**

Composition of the Board:

Chairman P. Scriven
Members: B. Noll
C. Almberg

Summary of Facts and Submissions

- I. The opponent appealed the decision by which the opposition against European patent 1383572 was rejected.
- II. In the statement of grounds of appeal, the appellant objected that claims 1 and 4 as granted did not comply with Article 100(c) EPC.
- III. In a communication accompanying a summons to oral proceedings, the Board gave its preliminary opinion that the subject-matter of claim 1 extended beyond the content of the application as filed, whereas claim 4 did not.
- IV. With its response, the proprietor submitted auxiliary requests 1 to 3. The response also contained the statement that (with the proprietor's emphasis) *we herewith request by **further auxiliary requests** for amended claims, which differ from the main request and the first auxiliary request in that feature 1.6 reads "means adapted to calculate a vector normal to the extracted cortical surface for each voxel in the 3D binary mask", respectively.* No text for these further auxiliary requests was provided.
- V. At oral proceedings before the Board, the proprietor withdrew auxiliary request 1, and submitted further auxiliary requests 1', 1'', and 1'''. The last of these has the claims as granted, but with the amendment to feature 1.6 intimated in its response to the summons (point IV, above), but no text was submitted.

- VI. At oral proceedings before the Board, the opponent's final request was that the appealed decision be set aside and that the patent be revoked.
- VII. The proprietor's final formulation of its requests was that the appeal be dismissed, i.e. that the opposition be rejected, i.e. that the patent be maintained as granted (main request), or that the patent be maintained as amended according to one of auxiliary requests 1', 1'', 1''', 2 or 3.
- VIII. The parties' submissions, in so far as relevant to the Board's decision, are given in detail in the reasons, below.
- IX. Claim 1 as granted reads (feature numbering by the Board, reflecting the numbering used before the Opposition Division):

A system for transcranial magnetic stimulation, comprising:

(1.1) a robotic member having a distal portion (310) and a proximal portion, said robotic member having at least six degrees of freedom;

(1.2) a coil (100) for generating an electric field, said coil (100) coupled to said distal portion (310) of said robotic member;

(1.3) means adapted to provide three dimensional (3D) images of the cortex;

(1.4) means adapted to extract cortical surfaces of said images of the cortex;

(1.5) means adapted to create a 3D binary mask of the cortical columns within the treatment volume of the subject;

(1.6) means adapted to calculate, for each voxel in the 3D binary mask, vectors normal to the extracted cortical surface;

(1.7) means adapted to use at least the normal vectors calculated for each voxel to calculate magnitude [sic] of the component of the E-field along cortical columns using the scalar product of the unit vector and the E-field;

(1.8) means adapted to generate a 3D scalar map of said component of the E-field;

(1.9) means adapted to compute a treatment plan based at least partly on said scalar map;

(1.10) a storage [sic] coupled to the computer and adapted to store said treatment plan; and

(1.11) a computer adapted to control movement of said robotic member and adapted to position said coil (100) using said treatment plan.

X. Claim 4 as granted reads

A method of planning optimal delivery of transcranial magnetic stimulation (TMS), comprising:

(4.1) imaging a subject to obtain an anatomical image, said anatomical image including a representation of a region of interest;

(4.2) obtaining a functional image of said subject in which said region of interest is selectively activated;

(4.3) identifying a target point from said region of interest via said functional image;

(4.4) modeling said anatomical image to obtain an anatomical model;

(4.5) co-registering said target point with said functional image and said anatomical model; and

(4.6) determining a position and orientation of a TMS stimulator so that maximum biological efficacy of said target point is obtained,

(4.6.1) the maximum biological efficacy at the target point being obtained using a 3D scalar map of said component of the E-field derived from the component of the E-field

*normal to cortical surfaces extracted from
said anatomical image,*

*(4.6.2) said map representing the E-field
magnitude along cortical columns.*

XI. Claim 1 of auxiliary request 1' differs from claim 1 of the main request in that feature 1.6 reads

*... means adapted to calculate vectors
normal to the extracted cortical surface,
wherein a vector is calculated for each
voxel within the 3D binary mask ...*

XII. Claim 1 of auxiliary request 1'' differs from claim 1 of the main request in that feature 1.6 reads

*... means adapted to calculate vectors
normal to the extracted cortical surface,
wherein a set of normal vectors is created
that uniformly fill each voxel within the
3D binary mask ...*

XIII. For claim 1 of auxiliary request 1''' see point IV, above.

XIV. Claims 1 of auxiliary requests 2 and 3 read as claim 4 of the patent as granted (see point X, above).

Reasons for the Decision

The main request

1. With claim 1 as granted, the proprietor purports to protect a system for stimulating the cortex of a human by an electric field. According to paragraph 2 of the patent specification, the electric field is generated by a wire coil by which an electric current induces a magnetic field which in turn induces an electric field in the human brain. Features 1.1, 1.2, and 1.11 of claim 1 define a robotic member, the coil, and a computer for controlling movement of the robot member. These elements constitute an "application" portion of the system by which the coil can be appropriately positioned during the stimulation. Features 1.4 to 1.10 define a "planning" portion by which, starting from a 3D image of the cortex, a treatment plan is established by calculating a component of the electric field generated by the coil along cortical columns as a 3D scalar map. The treatment plan is used for controlling movement of the robotic member.
2. Feature 1.6 of claim 1 defines that, for each voxel, vectors (plural) normal to the extracted cortical surface are calculated. A voxel in this context represents a volume element of the treatment volume of the cortex, which is represented by a 3D binary mask for executing the calculations for treatment planning.
3. The application as originally filed does not provide a direct and unambiguous basis for the calculation of a plurality of vectors normal to the extracted cortical surface for each voxel.

4. The proprietor argued that interpreting the word "vectors" as defining more than one vector per voxel was a linguistic misinterpretation. The wording of feature 1.6, interpreted in the light of the description as originally filed, meant that a plurality of normal vectors is calculated for the whole set of voxels, but only a single normal vector for each individual voxel. The proprietor referred to page 29, lines 13 - 14 of the published application (*The binary mask may be used to create a set of normal vectors that uniformly fill each voxel within the mask*) and to lines 18 - 19 (*A normal vector may then be calculated for each voxel within the binary mask from the gradient of EDM values [...]*).
5. The Board disagrees. The plain reading of "vectors" is plural, and the calculation is defined "for each voxel in the 3D binary mask". Therefore, claim 1 cannot be understood such that a single normal vector is calculated for each individual voxel.
6. The passages cited by the proprietor cannot change the plain meaning of the words used in a claim. Moreover, even if they could be invoked to change the plain meaning, they would not do so in the way for which the proprietor argues, let alone directly and unambiguously.
7. As regards the description on page 29 of the application as filed, the sentence bridging lines 13 to 14 does not define a relation between the number of calculated vectors and a single voxel. The expression that the vectors of the set "uniformly fill each voxel" is vague and does not indicate a number of vectors for a single voxel. This sentence could not serve as a basis for clarifying that a plurality of vectors is not

calculated for a voxel.

8. The second sentence referred to by the proprietor is part of a specific calculation process for calculating a normal vector, by "filling" the binary map with a Euclidean distance map of distances from the outer to the inner cortex, smoothing the distance map using a Gaussian filter, and calculating a vector for a voxel based on the smoothed gradient. This part of the description seems to be concerned with calculating "normal" vectors for voxels arranged between the outer surface and the inner surface. It is not concerned with the extraction of vectors at the surface, or with how many of those are extracted per voxel.
9. The Board, in its preliminary opinion, considered that the opponent's objections in the statement of grounds of appeal against claim 4 as granted related to clarity objections but not to added subject-matter. The Board does not see any reason to deviate from this view.
10. At oral proceedings before the Board, the opponent argued that, by defining that the maximum biological efficacy is obtained from the component of the E-field normal to cortical surfaces, but failing to specify that it is calculated as a scalar product of E-field vectors and cortical-column unit vectors, the subject-matter of the patent was extended to an undisclosed generalization.
11. This argument is not persuasive. The scalar product between vectors is, by definition, the component of one vector along the direction of the other. Defining that the maximum biological efficacy is obtained from the component of the E-field normal to cortical surfaces is, therefore, only a different way of expressing that

the scalar product of vectors is considered for obtaining maximum biological efficacy. This definition is not a generalization.

12. The opponent further argued at oral proceedings, that, for creating the 3D scalar map of the E-field component, coil parameters had necessarily to be taken into account, as disclosed on page 29 of the published application. By not defining this feature, the subject-matter of the patent was extended to an undisclosed generalization.
13. There are no exceptional circumstances which justify the raising of this new objection for the first time at oral proceedings. It could have been done earlier in the statement of grounds of appeal. The Board, exercising its discretion under Article 13(2) RPBA 2020, does not take this objection into account.
14. For the above reasons (points 1 to 7), the system of claim 1 as granted extends beyond the content of the application as filed. The ground for opposition under Article 100(c) EPC thus prejudices the maintenance of the patent as granted.

Auxiliary requests 1', 1'', 1''', and 2

15. Auxiliary requests 1' and 1'' were submitted during oral proceedings, and auxiliary requests 1''' and 2 were defined in wording or submitted with the proprietor's response to the summons (see point IV, above). Thus, these auxiliary requests were all submitted after notification of the summons to oral proceedings, after the entry into force of the revised Rules of Procedure of the Boards of Appeal (RPBA 2020).

Consideration of these requests is, therefore, by application of Articles 13(2) and 25 RPBA 2020, subject to the Board's discretion.

16. As regards the admission of auxiliary requests 1' and 1'', the patent proprietor argued that the essential arguments relating to the objection under Article 100(c) EPC were discussed in detail only at the oral proceedings before the Board. Therefore auxiliary requests 1' and 1'', which are a reaction to this objection, could not have been filed earlier.
17. The Board does not accept this argument. The objection under Article 100(c) EPC against claim 1 in respect of feature 1.6 had been raised in the Board's communication accompanying the summons, at point 16. A more detailed presentation at oral proceedings of arguments relating to an objection raised with the summons is not an exceptional circumstance and reason for submitting new requests at the oral proceedings.
18. As regards auxiliary request 1''', the amendment to feature 1.6 proposed in the proprietor's letter of 2 June 2021 does not clearly overcome the issue under Article 100(c) EPC without giving rise to further issues. The amendment is not, as argued by the patent proprietor, only a clarification to avoid a misinterpretation of the claim, but gives rise to the question whether it complies with Article 123(3) EPC. The patent proprietor did not submit any arguments in this respect.
19. As regards auxiliary request 2, which includes claims 4 - 7 as granted (renumbered as claims 1 - 4) and further dependent claims newly added, the patent proprietor argued that adding further method claims

would preserve some of the scope of the protection which the proprietor lost since system claims were held unallowable.

20. In the Board's view, the desire to preserve the protection of the patent with respect to an invalid system claim by adding dependent process claims as far as possible is not an exceptional circumstance and reason for submitting further dependent process claims late in the appeal proceedings when, as in the present case, the system claim was already attacked in the first instance proceedings.
21. Furthermore, a dependent claim cannot validly protect something that is not already protected by the claim from which it depends. The new claims, therefore, could not have the effect for which the proprietor argues.
22. Auxiliary requests 1', 1'', 1''', and 2, therefore, are not taken into account.

Auxiliary request 3

23. Auxiliary request 3 restricts the claims to method claims 4 to 7 as granted.
24. In its preliminary opinion, the Board expressed its view that claim 4 of the patent did not contain subject-matter which extended beyond the content of the application as filed (see point III, above). As a result, since the Board remains of the same view (points 9-13, above), auxiliary request 3 overcomes all the objections maintained in the opponent's appeal.

25. Moreover, the deletion of claims 1 - 3 as granted and the renumbering of the remaining claims neither affect the interpretation of those that remain, nor give rise to any new issue.
26. The amendment is, therefore, such that non-allowable claims are deleted and, as the proprietor has pointed out, only such claims remain for which the Board has already set out, in its communication accompanying the summons, that the objections raised against them were not persuasive (point 19). This particular constellation amounts to exceptional circumstances justified with cogent reasons for consideration of the request.
27. For these reasons, the Board takes auxiliary request 3 into account.
28. The Board concludes that the ground for opposition under Article 100(c) EPC does not prejudice the maintenance of the patent on the basis of auxiliary request 3.

Order

For these reasons it is decided that:

The appealed decision is set aside.

The case is remitted to the opposition division with the order to maintain the patent on the basis of auxiliary request 3, filed on 2 June 2021, and to adapt the description as necessary.

The Registrar:

The Chair:



H. Jenney

P. Scriven

Decision electronically authenticated