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**Datasheet for the decision  
of 25 May 2023**

**Case Number:** T 1903/19 - 3.4.01

**Application Number:** 12822877.2

**Publication Number:** 2739353

**IPC:** A61N2/02, A61N2/00, A61N2/06

**Language of the proceedings:** EN

**Title of invention:**  
LOW INTENSITY MAGNETIC FIELD DEVICES FOR TREATMENT OF CARDIAC  
AND NEUROLOGICAL DISORDERS

**Applicant:**  
University of Rochester

**Headword:**  
Low-intensity magnetic field devices / University of Rochester

**Relevant legal provisions:**  
EPC Art. 84, 123(2)  
RPBA 2020 Art. 13

**Keyword:**

Claims - clarity - main request and first to fourth auxiliary requests (no)

Amendment after summons - first auxiliary request taken into account (yes)

Amendments - added subject-matter present - fifth auxiliary request (yes)



**Beschwerdekammern**  
**Boards of Appeal**  
**Chambres de recours**

Boards of Appeal of the  
European Patent Office  
Richard-Reitzner-Allee 8  
85540 Haar  
GERMANY  
Tel. +49 (0)89 2399-0  
Fax +49 (0)89 2399-4465

Case Number: T 1903/19 - 3.4.01

**D E C I S I O N**  
**of Technical Board of Appeal 3.4.01**  
**of 25 May 2023**

**Appellant:** University of Rochester  
(Applicant) 601 Elmwood Avenue  
Box OTT  
Rochester, NY 14642 (US)

**Representative:** Michalski Hüttermann & Partner  
Patentanwälte mbB  
Kaistraße 16A  
40221 Düsseldorf (DE)

**Decision under appeal:** **Decision of the Examining Division of the  
European Patent Office posted on 7 February 2019  
refusing European patent application No.  
12822877.2 pursuant to Article 97(2) EPC.**

**Composition of the Board:**

**Chair** P. Scriven  
**Members:** T. Petelski  
C. Almberg

## **Summary of Facts and Submissions**

- I. The proprietor appealed the Examining Division's decision to refuse the European patent application for lack of clarity and lack of inventive step of both the main request and the auxiliary request.
  
- II. With their appeal, the appellant requested that the decision be set aside, and that a patent be granted based on the main request or auxiliary request, both as underlying the contested decision.
  
- III. In a preliminary opinion accompanying a summons to oral proceedings, the Board took a negative view on clarity and inventive step of the main request. Regarding the auxiliary request, the Board did not endorse the Examining Division's clarity objections but raised new objections of lack of clarity and added subject-matter, instead. Further, the Board also took a negative view on inventive step.
  
- IV. In response to the Board's preliminary opinion, the appellant filed new first, third, and fourth auxiliary requests. They also re-filed the (unchanged) main request and the previous (sole) auxiliary request, now labelled as second auxiliary request.
  
- V. During the oral proceedings, which took place via video link, the appellant filed a new fifth auxiliary request.

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

*A low intensity electromagnetic treatment device comprising:*

*a matrix of low intensity electromagnetic field coils;*

*a power source electrically connected to the matrix of low intensity electromagnetic field coils;*

*a control unit comprising control logic for addressing specific electromagnetic field coils;*

*a coordinate system for defining a location of specified low intensity electromagnetic field coils; and*

*a means for selectively energizing specified low intensity electromagnetic field coils to provide targeted magnetic treatment of specified regions of the head of a patient,*

*characterized by*

*a web comprising the matrix of low intensity electromagnetic field coils; and*

*a headband supporting the web for encompassing the head of a patient,*

*wherein the addressing of the specific electromagnetic coils contained in the matrix and the resulting magnetic field strength is performed by way of the coordinate system.*

VII. Claim 1 of the first auxiliary request is directed to a low intensity electromagnetic treatment device

*... for generating low intensity magnetic fields on the order of 0.01 Tesla, ... .*

Except for this addition to its introductory part, claim 1 is identical to claim 1 of the main request.

VIII. Claim 1 of the second auxiliary request is based on claim 1 of the first auxiliary request and differs from it in that:

(a) the last feature, starting with "wherein the addressing..." is moved to the end of the preamble;

(b) the first feature of the characterizing part reads (amendment underlined and reference signs omitted)

*... a web comprising and thereby determining the matrix of low intensity electromagnetic field coils;*

(c) the characterizing part gains a new last feature (reference signs omitted):

*...,  
wherein the matrix is an X-by-Y matrix and*

*the coordinate system used to address the coils contained on the matrix is a Cartesian coordinate system with the appropriate x or y axis variable is used in conjunction with a two digit variable that represents the nodes of the matrix.*

- IX. Claim 1 of the third auxiliary request differs from claim 1 of the second auxiliary request in that the last feature reads (amendment underlined, reference signs omitted):

*... ,  
wherein the matrix is an X-by-Y matrix and the coordinate system used to address the coils spanning the webbing of the matrix is a Cartesian coordinate system with the appropriate x or y axis variable is used in conjunction with a two digit variable that represents the nodes of the matrix.*

- X. Claim 1 of the fourth auxiliary request differs from claim 1 of the third auxiliary request in the last feature, which reads (amendment underlined, reference signs omitted):

*... ,  
wherein the matrix is an X-by-Y matrix and the coordinate system used to address the coils spanning the webbing of the matrix is a Cartesian coordinate system with the x or y axis variable of a specific coil is used in conjunction with two y or x axis*

*variables that represent the nodes that the specific coil spans.*

- XI. Claim 1 of the fifth auxiliary request is based on claim 1 of the first auxiliary request and differs from it in that the specification of the low intensity magnetic fields as "on the order of 0.01 Tesla" is replaced by "equal to or above 0.01 Tesla and below 0.1 Tesla".
- XII. The appellant's arguments, as far as they are relevant for the present decision, are reproduced in the Reasons for the Decision, below.

## **Reasons for the Decision**

### *Introduction*

1. The application describes the invention as a medical device that is adapted to provide "low intensity" magnetic or electromagnetic fields to a body part. The fields allegedly increase the respiratory control index values (RCI) of mitochondria, thereby improving the efficiency of these energy-producing organelles. This beneficial effect can be used for the treatment of various diseases. In some embodiments, intended for treatment of the brain, a plurality of individually addressable field generating coils is fixed to a web, which is held to the head of a patient with the help of a headband.

2. In examination proceedings, it proved difficult to distinguish the proposed devices from known medical devices that provide magnetic or electromagnetic fields to the body of a patient for other purposes, or even inadvertently.

*Main request - clarity*

3. Claim 1 is directed to "a low intensity electromagnetic treatment device comprising: a matrix of low intensity electromagnetic field coils" for providing "targeted magnetic treatment of specified regions of the head".
4. The relative und unspecific term "low intensity" was seen as problematic by the Examining Division.
5. According to the appellant, the skilled person would interpret the expression "low intensity" in the light of the description, which gave clear indications that "low intensity" referred to a field strength on the order of 0.01 Tesla. However, even without resorting to the description, the skilled person knew that magnetic fields of low intensity were those that could have easily been realized using conventional magnets. For example, a field with the strength of about five 5 mT, such as was generated by a typical refrigerator magnet, was clearly of low intensity. The appellant also cited the continuous exposure limit, for the general public, of 40 mT, issued by the International Commission on Non-Ionizing Radiation Protection (ICNIRP), as definitely being of low intensity.
6. These arguments are not persuasive. In the context of the (electro-) magnetic field intensity, the term "low" has no defined meaning and is, therefore, a relative

term. In the absence of an definition of what is is low in comparison to, it is unclear.

7. Relating intensity to a safety threshold or to the fields generated by typical household appliance magnets is arbitrary and not backed by the claim. With the same rationale, the field intensity could be related to the field generated by the human brain (smaller than 1 pT), the Earth's magnetic field (around 50  $\mu$ T), or to fields used by medical equipment like MRI (around 5 T).
8. The application emphasizes that the field strength is of utmost importance for the invention (see, for example, page 14, lines 6 - 26; and Figure 22). The field strength is, therefore, essential for the invention and must be defined in the claims by clear and unambiguous language. This is not the case for the relative term used in the definition of the "low intensity electromagnetic field coils".
9. Hence, the Examining Division did not err in finding that claim 1 is not clear (Article 84 EPC).
10. Hence, the main request is not allowable.

*First auxiliary request - admission*

11. The first auxiliary request was filed in response to the Board's preliminary opinion, sent with a summons to oral proceedings.
12. In its preliminary opinion, the Board had raised a new clarity objection against the (then) sole auxiliary request. The new first auxiliary request, prima facie, overcomes that objection. It is, prima facie, also a

promising attempt to tackle the clarity objection to claim 1 of the main request.

13. For these reasons, the Board used its discretion (Article 13 RPBA 2020) to admit the first auxiliary request into the proceedings.

*First auxiliary request - clarity*

14. Claim 1 defines the low intensity magnetic field as being "on the order of 0.01 Tesla".

15. The formulation "on the order of" defines a range. The question is whether this range has clearly defined boundaries, allowing the skilled person to know, whether they are working within the scope of the claim, or outside it.

16. Three mathematical interpretations were discussed during the oral proceedings before the Board:

(a)  $0.01 \text{ T} \leq B < 0.1 \text{ T}$  (values that lie in the same power of ten as 0.01)

(b)  $0.05 \text{ T} \leq B < 0.5 \text{ T}$  (values that can be rounded to 0.01)

(c)  $1/\sqrt{10} \times 0.01 = 0.0316 \text{ T} \leq B \leq \sqrt{10} \times 0.01 = 0.316 \text{ T}$   
(the upper bounds is 10 times the lower bound and 0.01 is at their geometric mean)

17. The appellant also argued for a medical definition, according to which the skilled person would only consider the range in which the desired effect of an increased RCI occurred. This could easily be verified

by experiments. The field of 0.01 T merely defined a suitable starting point for such experiments which could, for example, be carried out in steps of 0.001 T. The effect, naturally, did not disappear at a defined, sharp field strength. Hence, it was not appropriate to restrict the claim to a range with sharply defined borders.

18. In an alternative argumentation, the appellant argued that the medical definition and also at least one possible mathematical definition had to apply for the field to lie within the claimed range.
19. Ultimately, however, the appellant argued that the only possible understanding of the range was the mathematical definition (a).
20. A clear specification of the range of magnetic fields, including unequivocal end-points, is essential for the definition of the invention (cf. point 6.). However, the fact that there was such discussion of the possible boundaries of the claimed range demonstrates that there is no single, unambiguous meaning of "on the order of 0.01 Tesla". The expression could refer to one of several mathematical definitions of a range, to a medical definition of a range that is defined by its effect on the body, a combination of the two, or - using an everyday understanding of "of the order of 0.01 Tesla" - it could just mean "approximately 0.01 Tesla". All these are possible. However, they are all different, which is a first reason why the definition is unclear. Another reason is that, even if there were some indication as to which of them was meant, the range would still not be sufficiently defined, because none of them provides a clear definition of the boundaries:

- (a) The mathematical understanding of "on the order of" is ambiguous because there are at least the three different interpretations (a), (b), and (c) of what could be meant. The interpretation (a), which is favoured by the appellant, is no more likely than the other two.
  
- (b) The medical definition relies on the effect of the magnetic field on the patient. However, the effect is not defined in the claim beyond the very general definition "to provide targeted magnetic treatment of specified regions of the head of a patient". This definition covers a large variety of different treatments, requiring different effects. It is impossible to determine an exact range of magnetic fields based on an unspecified effect. Even if the effect highlighted in the description were assumed, which is the increase of the RCI of mitochondria, the borders of the claimed range would still be unclear. Figure 22 of the application shows a gradual change of the RCI with changing magnetic fields. It is, however, also not possible to determine clear boundaries from a gradually changing effect, without additional information.
  
- (c) The mathematical-medical understanding adds, to the clarity problems of each individual understanding, the additional problem that it is not clear, whether the intended range is the union of the individual ranges, or their intersection.
  
- (d) The everyday understanding of "on the order of" as "approximately" is fuzzy per se and does not define a range with exact boundaries.

21. It follows that the formulation "in the order of 0.01 Tesla" does not provide a clear definition of the boundaries of a range under each if its (at least) four incompatible understandings. Hence, the skilled person, and also a real-life third party, would be unable to know whether they were working within the claimed range or not. This means that claim 1 is not clear (Article 84 EPC).

22. Consequently, the first auxiliary request is not allowable.

*Second, third, and fourth auxiliary requests - clarity*

23. Claim 1 of each of the second, third, and fourth auxiliary requests has the same definition of the low intensity magnetic fields "on the order of 0.01 Tesla" as claim 1 of the first auxiliary request, without any further specification of this range.

24. Therefore, the claims are unclear for the same reason as claim 1 of the first auxiliary request (Article 84 EPC).

25. Consequently, the second, third, and fourth auxiliary requests are also not allowable, regardless of the matter of admission of the latter two.

*Fifth auxiliary request - added subject-matter*

26. Claim 1 differs from claim 1 of the first auxiliary request in that the definition of the low intensity magnetic fields "on the order of 0.01 Tesla" is

replaced by "equal to or above 0.01 Tesla and below 0.1 Tesla".

27. According to the appellant, this amendment, although not literally disclosed in the application as filed, was clearly and unambiguously derivable from it. Lines 15 to 18, on page 8 of the application, disclosed the magnetic field as being "on the order of 0.01 Tesla". Even though several definitions of "on the order of" were discussed in the context of the first auxiliary request, ultimately only one definition was correct. The expression "on the order of 0.01" could only refer to numbers in the same power of ten as 0.01, meaning the numbers equal to or above 0.01 and below 0.1 (the definition (a) referred to under point 16.). In the appellant's view, the skilled person would derive this mathematical range clearly and unambiguously from the application.
28. This is not persuasive. Page 8 contains two passages that mention a field of 0.01 Tesla. In the first passage, at the top of the page, the field of 0.01 Tesla is mentioned as an example of a suitable magnetic field strength, generated by the cardiac rhythm management device of Figure 1. In this embodiment, the field is generated at the target location in the myocardium (page 7, lines 23 to 29). In the second passage, in lines 15 to 17 of page 8, the exemplary field, "on the order of 0.01 Tesla", is generated by the implantable cardioverter defibrillator of Figure 2 at the target location in the ventricle of the heart (see also page 8, lines 14 to 24).
29. From these passages, the skilled person would learn that a field of 0.01 Tesla, or fields "of the order of" 0.01 Tesla, are suitable for achieving the desired

therapeutic effect when generated at the target location within the heart. Hence, considering the gradual change of the effect on RCI, the skilled person might assume that fields that are slightly lower or slightly higher than 0.01 Tesla might also work. For example, a field of 0.009 Tesla might well be considered to lie within "the order of" 0.01 Tesla. Hence, there is no basis for assuming that 0.01 Tesla is the lower bound of a suitable range of magnetic fields that extends up to 0.1 Tesla. There is no basis for this or for any other concretely defined range. In addition, there is no basis for the proposition that the field of 0.01 Tesla that works for the heart is also suitable for the head treatment device defined by the claims, and in which the magnetic field generating coils are located outside the head, at some distance from the target location. The respective Figures 10 to 17 do not mention any concrete field strength.

30. It follows that the application as filed does not provide a clear and unambiguous basis for a range of magnetic fields equal to or above 0.01 Tesla and below 0.1 Tesla, let alone that such fields are generated by a treatment device for the head (Article 123(2) EPC).
31. Hence, regardless of the question of its admission, the fifth auxiliary request is not allowable.

### *Conclusion*

32. The main request and the first to fourth auxiliary requests are not allowable, because their respective claims 1 are not clear.

33. The fifth auxiliary request is not allowable, because claim 1 extends beyond the content of the application as filed.

## Order

**For these reasons it is decided that:**

The appeal is dismissed.

The Registrar:

The Chair:



D. Meyfarth

P. Scriven

Decision electronically authenticated