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Datasheet for the decision
of 25 March 2021

Case Number: T 1556/16 - 3.4.01

Application Number: 09767831.2

Publication Number: 2294436

IPC: G01R33/38

Language of the proceedings: EN

Title of invention:
APPARATUS AND METHOD FOR DECREASING BIO-EFFECTS OF MAGNETIC GRADIENT FIELD GRADIENTS

Applicant:
Weinberg, Irving

Headword:
Magnetic field gradients / Weinberg

Relevant legal provisions:
EPC Art. 56, 83, 84, 123(2)
RPBA 2020 Art. 13(1), 13(2)

Keyword:
Amendment after summons - taken into account (yes)
Amendments - allowable (yes): limitation of range on the basis of an isolated value
Sufficiency of disclosure - (yes): open- vs closed-ended ranges
Inventive step - (yes)

Decisions cited:
T 1943/15

Beschwerdekammern

Boards of Appeal

Chambres de recours

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Case Number: T 1556/16 - 3.4.01

D E C I S I O N
of Technical Board of Appeal 3.4.01
of 25 March 2021

Appellant:
(Applicant)

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Bethesda, MD 20817 (US)

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Decision under appeal:

Decision of the Examining Division of the European Patent Office posted on 29 January 2016 refusing European patent application No. 09767831.2 pursuant to Article 97(2) EPC.

Composition of the Board:

Chairman P. Scriven
Members: A. Medeiros Gaspar
C. Almberg

Summary of Facts and Submissions

I. The appeal is against the decision of the Examining Division to refuse the European Patent application 09767831.2.

II. The Examining Division found the main request and auxiliary requests 1 to 4 before it not to be allowable. An auxiliary request 5, filed at the oral proceedings, was not consented to under Rule 137(3) EPC, and a subsequent request to continue in writing was rejected.

III. With the statement of grounds of appeal, the applicant requested that the decision be set aside and that a patent be granted on the basis of a new main request, identical to auxiliary request 2 of the impugned decision. Oral proceedings and consideration of new auxiliary requests 1 to 5 were also conditionally requested.

IV. In a communication accompanying the summons to oral proceedings, the Board expressed its provisional opinion. While disagreeing with the Examining Division, it considered claim 1 of the main request unallowable for other reasons. The auxiliary requests shared with the main request some of newly identified issues.

V. In reply, the appellant submitted further requests, among which a new main request and a new first auxiliary request, increasing the total number of requests on file to 25, and argued in favour of their consideration and allowability.

VI. In a further communication and subsequent telephone conversation, the Board noted some further issues with the new main and new first auxiliary requests.

VII. Shortly before oral proceedings the appellant submitted further auxiliary requests, based on auxiliary request 1, denoted 1(i) to 1(vii), and a further telephone conversation took place.

VIII. During oral proceedings, the appellant submitted a new main request, based on the auxiliary request 1(vii).

IX. At the end of the oral proceedings before the Board, the requests on file consisted of a main request submitted during the oral proceedings, followed by 32 auxiliary requests.

X. After deliberation, the Board came to the conclusion that the main request was allowable.

XI. Claim 1 according to the main request reads:

> *A method of implementing magnetic resonance imaging of structures containing neurological tissue, wherein the neurological tissue comprises at least a portion of a living organism, the method comprising:*
> *generating and applying to said tissue a sequence of magnetic field gradient pulses of an amplitude of at least 200 milliTesla per meter and not more than 1000 milliTesla per meter, wherein the magnetic field gradient is maintained at said amplitude during a plateau time period of at least one microsecond, and changed during rise-*

and fall-times both of less than 10 microseconds

XII. In what follows, reference is made to the following documents. D7 and D8 were discussed during examination proceedings, and D9 and D10 are mentioned in paragraphs [0013] and [0016] of the published application.

D7 P. T. While and L. K. Forbes : "Electromagnetic fields in the human body due to switched transverse gradient coils in MRI", PHYSICS IN MEDICINE AND BIOLOGY, INSTITUTE OF PHYSICS PUBLISHING, Bristol GB, vol. 49, no. 13, 7 July 2004, pages 2779-2798

D8 F. Schmitt. et al.: "Chapter 7: Physiological Side Effects of Fast Gradient Switching" In: "Echo-Planar Imaging", 1998, Springer-Verlag, Berlin Heidelberg, pages 201-252

D9 D. J. Schaefer et al.: "Review of Patient Safety in Time-Varying Gradient Fields", JOURNAL OF MAGNETIC RESONANCE IMAGING, vol. 12, no. 1, 2000, pages 20-29

D10 US 6 198 282 B1 6 March 2001

Reasons for the Decision

Main request - Admission

1. The main request was submitted during oral proceedings before the Board. It is based on auxiliary request 1(vii), that was itself based on auxiliary request 1, both also submitted after notification of the summons to oral proceedings.

2. All these requests constitute amendments to the appellant's case, the admission of which are at the Board's discretion under Articles 13(1) and (2) RPBA 2020.

3. The Board shall exercise its discretion under Article 13(1) RPBA 2020 in view of, inter alia, whether the amendment prima facie overcomes issues raised by the Board without giving rise to new objections. According to Article 13(2) RPBA 2020, any amendment to a party's case after notification of a summons to oral proceedings shall, in principle, not be taken into account, unless there are exceptional circumstances, which the party has justified with cogent reasons.

4. In the present case, these conditions for admission are met for the following reasons:

   (a) In the communication that accompanied the summons to the oral proceedings, the Board expressed its disagreement with the findings of the Examining Division, but, nevertheless, considered claim 1 of the main request to lack an inventive step, to be unclear, and to include unallowable amendments, for reasons that had not been previously identified by the Examining Division. The auxiliary requests had, among other issues, the same clarity and amendments issues as the main request.

(b) In that communication, the Board stated that the new issues were potentially remediable, and encouraged the appellant to provide its response in good time ahead of oral proceedings.

(c) The number of new requests submitted in reply was excessive. Nevertheless, at least new auxiliary request 1 was a valid response to the new issues, and could be recognised as overcoming all of them.

(d) However, the Board identified further new issues regarding sufficiency of disclosure and the allowability of amendments, which had not been identified in the summons(although they would have applied), to which the appellant once more reacted promptly, although the number of new requests was, again, excessive.

(e) With each submission, the appellant complied with its obligations under Article 13(1) and (2) RPBA 2020.

(f) The fact that the appellant was given the opportunity to respond to all the new issues ahead of the oral proceedings could, in some small degree, justify the high number of requests filed, since it was unclear which of the issues the Board had identified actually would finally prevent the grant of a patent.

(g) Once the appellant had filed its written submissions on all issues, it was clear that at least claim 1 of auxiliary request 1(vii) was allowable, and which issues remained to be addressed at the oral proceedings.

(h) The final amendment, filed during the oral proceedings, did no more than remove minor inconsistencies between independent claim 1 and dependent claims 2 and 3.

5. Therefore, in consideration of Article 13(1) and (2) RPBA 2020, the Board decided to take the main request, filed during the oral proceedings, into consideration.

The invention as disclosed

6. The invention concerns methods for implementing magnetic resonance imaging (MRI) of in vivo structures containing neurological tissue.

7. It addresses the desire of the in vivo MRI community to apply higher amplitude magnetic field gradients, while avoiding the undesirable bio-electrical effects that strong gradients tend to cause on that tissue (paragraphs [0002], [0019] and [0031]).

8. According to the invention, this is achieved by changing the gradients very rapidly. Concretely, if such changes are carried out over time periods of less than 10 microseconds, they are too fast for the neurological tissue to change its polarization state and are, therefore, effectively ignored (paragraphs [0034,0035] and [0080,0081]).

9. Hence, at such short time scales, magnetic field gradient pulses of any amplitude can, theoretically, be

applied, without eliciting undesirable bio-electrical effects. This includes amplitudes significantly above those employed in the prior art (paragraphs [0033], [0036], [0085] and [0086]).

10. The magnetic field gradient pulses employed in the prior art methods described in paragraphs [0003] - [0016] are said to have significantly longer rise and fall times, with the result that bio-electrical effects can be triggered.

11. At those (longer) time scales, certain threshold values for the amplitude of the magnetic field gradients, determined based on accepted theoretical models of the response of physiological tissue to magneto-stimulation, need to be observed, if bio-electrical effects are to be avoided (paragraphs [0012-0015]).

12. Consequently, the invention shortens the time needed for in vivo MRI, and increases spatial resolution (paragraphs [0018-0022]).

Main request, claim 1 -Clarity and Amendments' allowability

13. Claim 1 defines a method of implementing magnetic resonance imaging comprising generating, and applying to living neurologic tissue, a sequence of magnetic field gradient pulses with rise and fall times of less than 10 microseconds, and with an amplitude between 200 mT/m and 1000 mT/m.

14. It is based on original claim 5, with clarifications based on paragraphs [0080], [0081] and [0084], and further limitations based on Figure 7 and paragraphs [0084-0086].

15. The clarifications amount, in essence, to:

(a) the replacement of *in such a small time so as to fail to solicit a response from the neurological tissue exposed thereto*, which is formulated in terms of the desired result, by *in less than 10 microseconds*, which enables the result (see paragraphs [0080,0081] and [0084]); and

(b) the alignment of the terminology in the claim to that in paragraphs [0080,0081] and [0084].

16. The further limitations are to the amplitude of the magnetic field gradient pulses. It was originally defined as *at least 1mT/m*, but is now defined as *at least 200 mT/m and not more than 1000 mT/m*.

17. A direct basis for the upper limit of 1000 mT/m can be found in paragraph [0086] of the application, which teaches that *while the magnitude of the magnetic field is theoretically unbounded at its upper limit, it is foreseeable that the magnitude may be 1000 mT/m or less*.

18. Concerning the lower limit, original figure 7 and paragraph [0084] disclose a magnetic field gradient pulse according to the invention, with an amplitude 200mT/m.

19. Limiting an originally disclosed broader range using an isolated value taken from an example may be allowed, if it does not present the skilled person with information that goes beyond the content of the original disclosure (see Case Law Book II.E.1.5.2).

20. This is the case with the isolated value of 200 mT/m, used to limit the broader range starting 1 mT/m to the sub-range starting at 200 mT/m. The reasons for this are the following:

(a) As already indicated, the application teaches that, at time scales too short for bio-electrical effects to be triggered, any amplitude of the magnetic field gradient pulse may (theoretically) be employed, including amplitudes significantly higher than those employed in the prior art (paragraphs [0033],[0036], [0085] and [0086]).

(b) That such high amplitudes are particularly advantageous embodiments can be deduced from the explicitly-stated desire to reduce scan times and increase spatial resolution (paragraphs [0018-0022] and [0031]).

(c) The skilled person, therefore, understands the disclosure in connection to figure 6, depicting an example of a prior art magnetic field gradient pulse, and figure 7, depicting an example of a pulse according to the invention, as consolidating this general teaching with numerical values representative of the amplitudes and ranges alluded to in the general parts of the disclosure.

(d) Finally, the statement in paragraph [0086] that *while the magnitude of the magnetic field is theoretically unbounded at its upper limit, it is foreseeable that the magnitude may be 1000 mT/m or less*, confirms that the disclosure is not limited to the isolated value indicated.

21. Hence, the skilled person understands, from the original disclosure, that amplitudes from 200mT/m to 1000mT/m constitute particularly advantageous embodiments, and is not presented, by this particular selection, with new information.

22. Therefore, claim 1 complies with Article 123(2) EPC.

23. Claims 2 and 3 find basis in original claims 7 and 8, with minor clarifications for alignment with the wording of claim 1 and, hence, also comply with Article 123(2) EPC.

Main request, claim 1 - Sufficiency of disclosure

24. During the appeal proceedings, the possibility of claiming an amplitude range without an upper bound was considered. The point of concern was whether the original disclosure provided the skilled person with sufficient information for the implementation of the invention for arbitrarily high amplitudes.

25. While an open-ended range does not necessarily result in a lack of sufficiency of disclosure, the present open range is not limited in practice, as was the case in T 1943/15, mentioned by the appellant. In that case the quantity defined was a quotient which, by definition, could not take arbitrarily high or low values.

26. The fact that the application explains, in paragraph [0086], that the amplitude of the magnetic field gradient pulse is theoretically unbounded at its upper end does not mean the skilled person is able to put it into practice for arbitrarily high amplitudes.

27. The disclosure of paragraphs [0054-0065], in combination that of paragraph [0028], as well as that of paragraphs [0074-0079], in combination with that of paragraph [0030], are sufficient to enable the generation of a sequence of pulses with rise and fall times of less than 10 microseconds, at a variety of amplitudes including above those employed in the prior art. Still, such disclosures does not enable the generation of arbitrarily high magnetic field gradients.

28. The present main request avoids this issue, by means of the upper limit of 1000 mT/m.

29. The Board finds that the above-mentioned passages of the application are sufficient to enable the skilled person to generate magnetic field gradients pulses with rise- and fall-times of less than 10 microseconds and an amplitude of less than 1 T/m.

30. Therefore the main request complies with Article 83 EPC.

Main request, claim 1 - Inventive step

31. An assessment of inventive step requires consideration of the state of the art (Article 56 EPC).

32. Of the documents on file, D7-D10 relate to in vivo MRI and are furthermore concerned, as is the application, with the need to avoid the triggering of undesired bio-electric effects, in particular in nerve tissue. These documents also have the most features in common with the subject-matter of the present main request. As

such, documents D7-D10 represent the most appropriate starting points for an assessment of inventive step.

33. Claim 1 of the main request differs from the disclosure of each of D7-D10 by the properties of magnetic field gradient pulses. Concretely, none of these documents discloses the use of pulses with rise and fall times of less than 10 microseconds and amplitudes between 200 mT/m and 1000 mT/m.

34. As already mentioned, pulses with such properties enable quicker and higher spatial resolution *in vivo* acquisitions, while avoiding to elicit undesirable physiological responses from the neurological tissue.

35. The question to be answered is then whether, having regard the state of the art as disclosed in D7-D10, the skilled person would have employed a sequence of magnetic field gradient pulses with the recited properties, when seeking to achieve either of the above-mentioned results.

36. For reasons that will be further detailed below with regards to each of the documents, the Board has come to the conclusion that, even if the skilled person would (at least in view of the disclosures of documents D8 and D9) have employed pulses with rise and fall times in the microsecond range, at least to reduce the acquisition times, those pulses would still have been of an amplitude significantly below the defined range.

37. This is because the prior art does not teach, or suggest, that by employing magnetic field gradient pulses with rise and fall times of less than 10 microseconds, amplitudes significantly higher than the thresholds determined based on accepted physiological

models could be employed without eliciting a physiological response.

38. When examining other requests, the Examining Division came to the conclusion that, having regard the prior art disclosure of document D7, the skilled person would have considered employing magnetic field gradient pulses with rise and fall times of less than 10 microseconds.

39. The Board does not share this view and furthermore notes that the Examining division failed to indicate the technical effect associated with the difference identified.

40. Document D7 is concerned with the simulation of the electric field induced in neurological tissue by a magnetic field gradient pulses.

41. The results of such simulations are depicted in figures 7 and 8 of D7, for two amplitudes of said magnetic field gradient pulse (10mT/m and 40mT/m), as a function of the rise time over which the magnetic field is changed. The simulated induced electric field curves are depicted superimposed on curves modelling the stimulation threshold of neurological tissue, both varying with the pulse rise time.

42. From the scale of figures 7 and 8, as well as from the corresponding discussion on page 2795, a reliable interpretation of the results for rise times significantly below 100 microseconds, in particular below 10 microseconds, is not possible. That a possible crossing of the lines depicted in figure 8 at rise times significantly below 100 microseconds is accorded no relevance in D7 is, in the Board's view, also made

clear by the explicit statement, on page 2795, that between 0 and 800 microseconds, the induced electric field greatly exceeds the nerve stimulation threshold.

43. The discussion of the results provides the skilled person seeking to avoid bio-electric effects with no motivation to deviate from the rise time scales disclosed, especially not in the direction of lower rise-times.

44. In fact, D7 teaches the skilled person that the shorter the pulses rise- and fall-times, the lower the pulse amplitudes need to be; or, conversely, that the higher the amplitudes of the magnetic field gradient pulses, the longer the pulse rise- and fall-times are required to be.

45. Therefore, starting the disclosure of document D7 the skilled person would not have arrived at a sequence of magnetic field gradient pulses with rise- and fall-times of less than 10 microseconds, let alone combined with an amplitude between 200 and 1000 mT/m.

46. D10 also discloses magnetic field gradient pulses with rise- and fall-times on the order of hundreds of microseconds, and also teaches that, for such time scales, higher magnetic field gradients, and hence higher spatial resolution, require longer rise- and fall-times, or lower slew rates, as can be derived from the disclosure of figure 5 and column 5 lines 56-63, taking into consideration the disclosure of figure 3 and column 3, line 60 to column 4, line 7. In fact, for the highest slew rate indicated in figure 5, of some 35 G/cm/ms, one obtains, based on the modelled physiological limit curve 12, a maximum threshold amplitude of some 3.5 G/cm (corresponding to 35 mT/m),

from which a minimum pulse width of 100 milliseconds is obtained.

47. Figure 5 of D10 also indicates that, for higher amplitudes, significantly longer rise-times would be needed. For instance, for the maximum amplitude depicted of 10 G/cm (100 mT/m), a pulse rise-time of more than 500 microseconds would be required.

48. Hence, in view of the disclosure D10, the skilled person would not have employed pulses with rise- and fall-times of less than 10 microseconds, let alone in combination with amplitudes within the range of 200 mT/m to 1000 mT/m.

49. D9 reports on experimental studies on humans, validating the physiological models behind the threshold curves for pulses of rise times below 100 microseconds.

50. The experimental evidence presented in D9 (figures 6 and 7) does not disclose the application of magnetic field gradient pulses with rise-times as low as 10 microseconds. It does, however, present, on table 1, an extrapolation of those models to rise-times below 10 microseconds.

51. It is debatable whether the skilled person would, in view of this extrapolation, have employed magnetic field gradient pulses with rise- and fall-times scales below 10 microseconds, given the lack of experimental validation.

52. In any case, even if she did, she would have employed magnetic field gradient pulses of an amplitude at most up to the estimated threshold values indicated in table

1. This would still fall significantly below the range defined in the claim, for the following reasons:

(a) To all three threshold values of the parameter dB/dt, indicated for a ramp times of 10 microseconds or less, the corresponding amplitude of the gradient Bmax=dB/dt*dt is less than 8 mT.

(b) The amplitude in mT/m is obtained by dividing the Bmax in mT by a distance of the order of tens of centimeters, related to distance (field of view) over which the gradient of the field changes linearly. Considering a distance of some 20 cm (see e.g. figure 1 of D9), one obtains an amplitude of Bmax of less than 40 mT/m.

53. Hence, even if, in view of the disclosure of document D9, the skilled person would have employed magnetic field gradient pulses with rise- and fall-times below 10 microseconds, she would not have employed amplitudes within the range recited in the claim.

54. D8 reports, on pages 224-228, table 4 and figure 18, on the recommendations by different countries on the time-varying magnetic fields dB/dt to be applied in *in vivo* MRI, in view of the need to avoid the triggering of undesirable bio-electric effects on living tissue. Different thresholds are indicated for different ranges of a parameter τ, corresponding to twice the rise-time of a magnetic field gradient pulse.

55. It is immediately apparent from figure 18 of D8, that the application of pulses with τ< 20 microseconds, corresponding to rise- and fall-times of less than 10 microseconds, are both contemplated and regulated.

56. The person skilled in the art would, then, have considered employing magnetic field gradient pulses with rise- and fall-times in the microseconds range, when addressing the problem of reducing acquisition times.

57. She would, however, not have employed amplitudes above those corresponding to the threshold values indicated, which (once more) are significantly below those in the claim. This is because she would have understood, from the disclosure of a level of no concern and a level of concern (in table 4), that the triggering of undesired firing of nerves would be almost unavoidable above the latter values.

58. In fact, in view of the need to avoid undesirable bio-electric effects on the living tissue imaged, it is even questionable whether the skilled person would ever have considered pulses of an amplitude within the range of concern. Still, even considering the extreme example, with variations of 1330 T/s applied in rise and fall times of 10 microseconds (IEC threshold for level of concern), the amplitude of the pulses would still be less than 13 mT, which (over some 20 cm) leads an amplitude of of less than 65 mT/m.

59. Hence, also in view of the disclosure of document D8, the skilled person would not have arrived at employing magnetic pulse gradients with rise and fall times of less than 10 microseconds and amplitudes between 200 mT/m and 1000 mT/m in an obvious manner.

60. Therefore, the subject-matter of claim 1 of the main request entails an inventive step.

Final comments on the decision appealed

61. The appealed decision was not based on present main request. Its reasoning also does not impact this decision, other than indirectly in two points.

62. One of those points is the reasoning on inventive step over the disclosure of D7, in paragraph 2.3.2 of the appealed decision, which could be seen as indirectly impacting the inventive step assessment of the present main request (see paragraphs 38 to 45 above).

63. The other relates to the decision of the Examining Division not to consent to the auxiliary request 5, submitted to them during oral proceedings(appealed decision at 2.6, 2.6.1, and 2.6.2).

64. The statement at 2.6.1 of the decision, that a request limiting the gradient amplitudes to above 100 mT/m would have necessitated a further search seems to be incorrect, for the following reasons:

(a) The supplementary European search report established for this application indicated that a full search was carried out. Such a search covered original method claims 4-8, defining an interval with an open upper end for the magnitude of the magnetic field gradients, under which the claims of the present request fall.

(b) Even though the original claim defined a broad range of magnetic field gradient amplitudes, the original application emphasised the desirability of higher-amplitude pulses and made the increases aimed at concrete with the disclosure of specific examples (see, paragraphs [0019] and [0031], and figures 6 and 7 and paragraphs [0082-0086]). In this context, if the Search Division had not covered high amplitudes in its search, it would have indicated as much.

65. It is also noted that previous requests had already indicated the applicant's intent to pursue high-amplitude gradients, or high slew rates. In fact, the late introduction of documents D7 and D8 is a result of the convergence of the proceedings in that direction.

66. Therefore, only the reasons presented under item 2.6.2 of the decision (in apparent contradiction to the statements at 2.6.1) support the decision not to consent to the fifth auxiliary request. The lateness of the submission and its *prima facie* unsuitability for solving all the pending issues, were appropriate considerations.

67. The Board further notes that the fifth auxiliary request was attached neither to the decision, nor to the minutes of the oral proceedings, and there is no record of it in the file. This, effectively prevents the Board from fully revising the decision taken.

68. Finally, the reasons why the request for a continuation of the proceedings in writing was rejected are not apparent from the decision, but are, fortunately, recorded in the minutes of oral proceedings. When faced with a new prior art document (D7), two weeks ahead of oral proceedings, the applicant had been offered the option of continuing in writing, but had rejected the offer. This renders moot the appellant's argument that its auxiliary request 5 should have been considered since D7 was also introduced very late.

Order

For these reasons it is decided that:

The decision under appeal is set aside.

The case is remitted to the Examining Division with the order to grant a patent on the basis of the main request, submitted during oral proceedings before the Board, the original drawings, and a description to be adapted as necessary.

The Registrar: The Chair:

D. Meyfarth P. Scriven

Decision electronically authenticated