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Datasheet for the decision of 11 June 2012

Case Number: T 1748/08 - 3.2.02

Application Number: 99958852.8

Publication Number: 1128764

IPC: A61B 5/0478

Language of the proceedings: EN

Title of invention:
fMRI compatible electrode and electrode placement techniques

Applicant:
Compumedics Limited

Opponent:
-

Headword:
-

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

Keyword:
"Inventive step (main request): no"
"Admissibility of auxiliary requests: no"

Decisions cited:
-

Catchword:
-

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Case Number: T 1748/08 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 11 June 2012

Appellant: (Applicant)
Compumedics Limited
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Representative:
Hands, Lewis Roger
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Decision under appeal:
Decision of the Examining Division of the European Patent Office posted 20 February 2008 refusing European patent application No. 99958852.8 pursuant to Article 97(2) EPC.

Composition of the Board:

Chairman: E. Dufrasne
Members: C. Körber
P. L. P. Weber

Summary of Facts and Submissions

I. On 20 February 2008 the Examining Division posted its decision to refuse European patent application No. 99958852.8 for lack of inventive step.

II. An appeal was lodged against this decision by the applicant by notice received on 17 April 2008, with the appeal fee being paid on the same day. The statement setting out the grounds of appeal was received on 1 July 2008, accompanied by a "Statement from Person Skilled in the Art" dated 27 June 2008 and signed by Mr. C. M. Andrew.

III. By communication of 15 March 2012, the Board summoned the appellant to oral proceedings and forwarded its provisional opinion.

IV. With letter received via online filing at 20:02h on Friday, 8 June 2012, the appellant submitted a 1st and a 2nd auxiliary request.

V. Oral proceedings were held on 11 June 2012. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the set of claims filed in the first instance proceedings with letter of 13 June 2005 (referred to as the "main request" hereinafter), or on the basis of one of the above-mentioned auxiliary requests. It further submitted an (undated) printout from Wikipedia entitled "Functional magnetic resonance imaging".

VI. The following document is of importance for the present decision:

D1: US-A-5 445 162.

VII. Claims 1 and 14 of the main request read:

"1. Apparatus for collecting physiological electrical signals inside of a shielded environment of a functional magnetic resonance imaging system (fMRI) during normal operation of the fMRI system and for communicating them outside of the shielded environment, the apparatus comprising:
one or more electrodes (30; 40, 41; 50, 51; 60; 70; 80);
one or more non-amplifying electrode leads (13) connected to said electrodes;
characterised in that the electrode leads (13) are configured to conduct signals over a distance of more than 3 metres (10 feet) without amplification;
and in that the apparatus further comprises an amplifier system located outside of the shielded environment and connected to said leads (13), and means for collecting and processing the signal data connected to the output of the amplifier system;
the signals being thereby communicated without interfering with the integrity of the fMRI data."

"14. A method for collecting electrical data inside of a shielded environment of a functional magnetic resonance imaging (fMRI) system during normal operation of the fMRI system without interfering with the integrity of the fMRI data, the method comprising steps of:

placing one or more electrodes (30; 40, 41; 50, 51; 60; 70; 80) in dermal contact with a patient located inside of the shielded environment;
connecting said electrodes to one end of a non-amplifying lead wire (13) that is disposed inside the shielded environment; and
connecting a second end of said lead wire (13) to an amplifier system located outside of said shielded environment."

Claims 2 to 13 and 15 to 20 are dependent claims.

Claim 1 of the 1st auxiliary request reads:

"1. An electrode assembly, comprising one or more electrodes (30, 40, 41, 50, 51, 60, 70, 80) connected to electrode leads (13) configured to carry electrical signals while operating inside a functional magnetic resonance imaging (fMRI) system during normal operation without interfering with the integrity of fMRI data, characterised in that the electrode leads (13) are enclosed by a flexible material, wherein the flexible material is configured to prevent coiling of said electrode leads (13)."

Claim 1 of the 2nd auxiliary request reads:

"1. Apparatus for collecting physiological electrical signals inside of a shielded environment of a functional magnetic resonance imaging system (fMRI) during normal operation of the fMRI system and for communicating them outside of the shielded environment, the apparatus comprising:
one or more electrodes (30, 40, 41, 50, 51, 60, 70, 80);

one or more non-amplifying electrode leads (13) connected to said electrodes;
characterised in that the electrode leads (13) are configured to conduct signals over a distance of more than 3 metres (10 feet) without amplification;
the apparatus further comprising:
an amplifier system located outside of the shielded environment and connected to said leads (13);
means for collecting and processing the signal data connected to the output of the amplifier system;
flexible material enclosing the electrode leads (13), the flexible material being configured to prevent coiling of said electrode leads;
the signals being thereby communicated without interfering with the integrity of the fMRI data."

VIII. The appellant's arguments are summarised as follows:

The person skilled in the art of the field of invention was an ordinary practitioner who was knowledgeable about the specific aspects of the measurement of EEG signals in an fMRI environment, and not simply a person who has knowledge of the field of electromagnetic measuring. The field of electromagnetic measuring was a hugely broad field which did not necessarily include knowledge of the peculiarities of measuring EEG signals in an fMRI environment. This also became evident from the statement of Mr. Andrew filed with the grounds of appeal.

Dl did not relate to exactly the same technical field as that of the invention because the system disclosed in Dl was a conventional MRI system and not a functional MRI (fMRI) system. Putting aside the fact that Dl did not disclose an fMRI system, the primary difference between

Dl and the invention of claim 1 was that Dl did not disclose a system which incorporated electrode leads that were configured to conduct signals over a distance of more than 3 metres, and that Dl did not disclose a system in which an amplifier was located outside of a shielded environment.

The technical effect brought about by this difference over D1 was the reduction of interferences between the EEG system and the MRI system. The objective technical problem was to improve the quality of EEG signals and the quality of MRI measurements. As could be seen from the submitted printout from Wikipedia (top of page 3), fMRI had the particular disadvantage of a poor signal-to-noise ratio, necessitating extensive post-processing.

In all embodiments disclosed in Figures 1 to 3 of Dl the amplifier 40 was positioned inside the shielded MRI environment 20. Dl did not teach or even suggest extending the length of the leads 34 to a distance of more than 3 metres or moving the amplifier 40 to outside the shielded MRI environment 20. The fact that this would not have been obvious to the person skilled in the art was also clear from the statement of Mr. Andrew. The general knowledge of persons skilled in the art, as supported by this statement, was that an EEG amplifier should be positioned inside a shielded MRI environment. To position an EEG amplifier outside of the shielded MRI environment would have gone against the general understanding in this particular field of technology.

The very late submission of the auxiliary requests on 8 June 2012 was due to the fact that the new representative had only been recently appointed to the

case at issue and only received instructions as to these requests on that date.

Claim 1 of the 1st auxiliary request was based on original claim 1 amended by the insertion of original claims 6 and 7. Further support could be found in the description at page 6, lines 11 et seq.

Claim 1 of the 2nd auxiliary request had been amended by the insertion of the features of claims 6 and 7 into claim 1 as refused by the Examining Division. It thus corresponded essentially to a combination of claim 1 of the main request with claim 1 of the 1st auxiliary request.

Reasons for the Decision

1. The appeal is admissible.

2. Main request - inventive step

Document D1, which is acknowledged in the second paragraph of page 2 of the original application as published (WO-A-00/27279), is regarded as the closest prior art. It discloses, in the wording of claim 14 of the main request (which is the broadest independent claim of this request, in particular since it does not include the limitation of independent claim 1 concerning the configuration of the electrode leads to conduct signals over a distance of more than 3 metres without amplification), a method for collecting electrical data inside of a shielded environment (20) of a functional magnetic resonance imaging (fMRI) system (22) during

normal operation of the fMRI system without interfering with the integrity of the fMRI data, the method comprising steps of:
placing one or more electrodes (30) in dermal contact with a patient located inside of the shielded environment (column 2, lines 64-66);
connecting said electrodes to one end of a non-amplifying lead wire (34) that is disposed inside the shielded environment (Figure 2); and
connecting a second end of said lead wire to an amplifier system (40).

Even though there is no explicit disclosure in D1 that MRI room 20 is actually "shielded", the walls of the room are considered to provide some kind of "shielded environment", in accordance with the appellant's view. Similarly, the inside of the housing of the MRI machine 22 could be regarded as a "shielded environment". However, in the Board's view, such an interpretation does not appear to be sufficient to justify a novelty objection against the feature of the amplifier system being located outside of said shielded environment based on the embodiment shown in Figure 2 of D1, where the amplifier 40 is depicted outside the MRI machine 22.

In spite of the fact that it is acknowledged in lines 3 to 4 of page 2 of the application that D1 deals with the collection of EEG signals within an **f**MRI environment, the appellant argued that D1 only discloses a conventional MRI system, and not a functional MRI (fMRI) system. However, in lines 14 to 26 of column 1 of D1 it is stated that its objective is to record an EEG pattern in an MRI machine that provides **metabolic** and anatomical information about the brain. The blood-oxygen-level

dependent ("BOLD") contrast evaluated in fMRI is due to the hemodynamic response resulting from the increased energy demand of stimulated neurons, i.e. their metabolism. This is also indicated in the printout from Wikipedia about fMRI submitted by the appellant during oral proceedings (page 1, second paragraph). A merely conventional MRI would not provide meaningful results that could be correlated with the neurophysiological phenomena detected by an EEG, which is the field of the invention underlying D1 (column 1, lines 9 to 11). Accordingly, in the Board's view, D1 anticipates the collection of electrical data in a functional magnetic resonance imaging system even though the term "functional" does not occur verbatim.

Consequently, the only distinguishing feature of claim 14 over D1 is that the amplifier system is located outside the shielded environment. Locating the amplifier system outside of a shielded environment is also stated to be the "primary difference" over D1 in the grounds of appeal.

The technical effect of locating the amplifier system outside the shielded environment is the reduction of contamination of the anatomical and functional data acquired by the fMRI system due to electro-magnetic interferences caused by the amplifier system (sentence bridging pages 1 and 2 of the application).

The objective technical problem to be solved by the claimed invention is to improve the integrity of the acquired data.

The person skilled in the art aiming to solve this problem is knowledgeable about the technical field of the measurement of electrical signals in an fMRI environment. In contrast to the appellant's view, his knowledge is not limited to the very specific peculiarities of measuring EEG signals in an fRMI system, but also covers basic aspects of electromagnetic measurements in general, e.g. noise effects and electromagnetic interferences. The fourth paragraph of page 1 of the statement of Mr. Andrew provided by the appellant with the statement of grounds of appeal, where it is stated that it was known that the amplifier should be positioned as far as possible from the MRI device in order to avoid interferences, actually seems to confirm this definition of the skilled person.

D1 itself already addresses the issue of interferences of radio frequency sources associated with the EEG equipment with the diagnostic quality of the MRI images (column 1, lines 36 to 41) and provides the general teaching to move "all significant radio frequency generating equipment outside the MRI room" when EEG signals are to be recorded and MRI images to be obtained simultaneously (column 1, lines 60 to 66). Furthermore, D1 discloses that the EEG signals are "transmitted to an amplifier that is positioned sufficiently far away from the patient's head so as to prevent distortion of the MRI" (column 2, lines 5 to 9). Accordingly, with this general information given in D1 the skilled person is already made explicitly aware of the fact that an amplifier may cause distortion of the MRI images and thus forms part of the "significant radio frequency generating equipment" that should be located outside the MRI room. The "Summary of the Invention" of D1 thus

provides a clear and unambiguous hint towards the distinguishing feature of claim 1.

As stated in column 3, lines 26 to 32 of D1, a distance of at least five centimetres between the electrodes and the amplifier was considered necessary in order to avoid image distortion, but it was preferred to position the amplifier outside the bore of the MRI magnet as shown in Figure 2, i.e. at a considerably larger distance away. It is true that all the specific embodiments of D1 as depicted in Figures 1 to 3 show the amplifier 40 as being located inside the MRI room 20. However, there is no teaching in D1 that the "EEG amplifier should always be located inside the shielded environment", as asserted by the appellant. The fact that in the drawings of D1 the amplifier is depicted inside the MRI room would not prevent the skilled person from considering a positioning outside thereof, particularly in view of the general hint given in the introductory portion of D1 as mentioned above. Furthermore, this does not "go against the general understanding in this particular field of technology". When trying to find a compromise between the counter-acting requirements of minimising electromagnetic disturbances of fMRI images due to the EEG equipment (achievable by positioning the amplifier system as far as possible away from the MRI machine) and maintaining an acceptable signal-to-noise ratio of the weak EEG signals (which decreases with increasing distance), the skilled person would also try to position the amplifier system outside of the MRI room, being well aware of the generally known protective effect of its walls regarding electromagnetic interferences, if the EEG signal quality was still sufficient in this position. The length of the leads 34 as depicted in Figure 2 would

not even have to be extended in order to be connected to an amplifier 40 located outside the MRI room 20. The above-mentioned counter-acting requirements are explicitly mentioned in D1 (column 1, lines 36 to 44). D1 deals with functional MRI as explained above and specifically addresses the problem of distorted image quality. Accordingly, the skilled person, defined as indicated supra, is aware of the fact that fMRI techniques generally have a poor signal-to-noise ratio, thereby necessitating extensive post-processing, as pointed out by the appellant with reference to the above-mentioned printout from Wikipedia. Being aware of this problem and the protective effect of the walls of the MRI room, the skilled person would position the amplifier system outside the MRI room 20 even though such a location is not depicted in D1.

It follows that the subject-matter of claim 14 is obvious from D1 and common general knowledge and thus does not involve an inventive step within the meaning of Article 56 EPC.

3. 1st and 2nd auxiliary requests - admissibility

The sets of claims filed as 1st and 2nd auxiliary requests constitute amendments which were submitted after the grounds of appeal had been filed. Pursuant to Article 13(1) RPBA, their admittance lies within the Board's discretion, which has to be exercised in view of inter alia the current state of the proceedings, the complexity of the new subject-matter and the need for procedural economy.

In the present case, the requests at issue were in fact submitted so late that they reached the attention of the Board only immediately before the beginning of the oral proceedings, i.e. at a very late state of the proceedings. As a justification for the late filing, the appellant's representative indicated that he had only recently been appointed to the case. However, according to the established case law of the boards of appeal, a change of representative usually results from the party's own decision and is generally not an acceptable ground for late filing ("Case Law of the Boards of Appeal of the EPO", 6th ed. 2010, VII.C.1.5.3). In the present case, the Board cannot recognise any special circumstances that would justify deviating from this principle.

Even at such a late stage of the proceedings, the Board would in some cases still admit amendments which make the request prima facie allowable, for reasons of procedural economy. Such amendments should in principle allow the granting of a patent based thereon. However, in the present case this criterion is not fulfilled for the following reasons. With respect to the basis of claim 1 of the 1st auxiliary request, the appellant has indicated that claim 1 as originally filed had been amended by the insertion of the features of original claims 6 and 7. However, whilst claim 7 relates back to claim 6, the latter only refers to claim 4, which specifies various materials from which the electrode leads are manufactured, and these features of claim 4 were not included in the new claim 1. Moreover, claim 6 requires that "at least two electrode leads" are enclosed by a flexible material, whereas new claim 1 merely refers to "the electrode leads" in this regard.

Since "electrode leads" are mentioned at the beginning of the claim, the new wording suggests that all these electrode leads are enclosed by a flexible material, and it remains questionable whether this amendment is supported by the application as originally filed. The passage in lines 11 to 12 of page 6 of the original description referred to by the appellant during the oral proceedings does not provide clear support in this respect either since it merely mentions that the lead wires may be **wrapped in groups** with flexible wrapping material. Accordingly, the Board already has serious doubts whether claim 1 of the 1st auxiliary request fulfils the requirements of Article 123(2) EPC. Under these circumstances, it cannot be said that the request is prima facie allowable, and there is no need to examine whether the respective objections regarding patentability raised by the Examining Division in its very first communication dated 26 November 2003 (see items 3.2 and 3.3) are still applicable or whether the remaining requirements of the EPC are fulfilled.

Since the above-mentioned deficiencies objectionable under Article 123(2) EPC are also present in claim 1 of the 2nd auxiliary request, this request is also not prima facie allowable.

Under the given circumstances, the Board does not admit the 1st and 2nd auxiliary requests under Article 13(1) RPBA.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

D. Hampe E. Dufrasne