Datasheet for the decision of 1 September 2011

Case Number: T 0780/09 - 3.4.01
Application Number: 07010270.2
Publication Number: 1860453
IPC: G01R 33/563
Language of the proceedings: EN

Title of invention:
Diffusion-weighted MRI

Applicant:
Kabushiki Kaisha Toshiba, et al

Opponent:
-

Headword:
-

Relevant legal provisions:
RPBA R. 13

Relevant legal provisions (EPC 1973):
EPC Art. 56

Keyword:
"Late-filed (admitted: main request, first to third auxiliary request, not admitted: fourth auxiliary request)"
"Inventive step (no, all admitted requests on file)"

Decisions cited:
-

Catchword:
-
Case Number: T 0780/09 - 3.4.01

DECISION
of the Technical Board of Appeal 3.4.01
of 1 September 2011

Appellant:
Kabushiki Kaisha Toshiba
1-1, Shibaura 1-chome
Minato-ku
Tokyo (JP)

Representative:
Kramer - Barske - Schmidtchen
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Decision under appeal:
Decision of the Examining Division of the European Patent Office posted 27 November 2008 refusing European patent application No. 07010270.2 pursuant to Article 97(2) EPC.

Composition of the Board:
Chairman: B. Schachenmann
Members: H. Wolfrum
P. Fontenay
Summary of Facts and Submissions

I. European patent application 07 010 270.2 (publication No. EP-A-1 860 453) was refused by a decision of the examining division dispatched on 27 November 2008, inter alia for the reasons of lack of novelty and inventive step (Articles 52(1), 54(1) and (2) and 56 EPC 1973) of the subject-matter of the requests then on file.

II. The applicants lodged an appeal against the decision and paid the prescribed fee on 27 January 2009. On 20 March 2009 a statement of grounds of appeal was filed. The appellants requested the grant of a patent on the basis of amended sets of claims according to a main request and three auxiliary requests. Furthermore, an auxiliary request for oral proceedings was made.

III. On 15 April 2011 the appellants were summoned to oral proceedings.

In a communication annexed to the summons, the Board gave a preliminary opinion inter alia on the issue of inventive step based on documents:

D1: D. Ballon et al: "Imaging Therapeutic Response in Human Bone Marrow Using Rapid Whole-Body MRI", Magnetic Resonance in Medicine, vol. 52, 2004, pages 1234-1238; and

IV. In response, the appellants filed by letter of 27 July 2011 new sets of claims according to a main request and three auxiliary requests.

V. Oral proceedings were held on 1 September 2011.

As a result of the discussion, the appellants requested that the decision under appeal be set aside and a patent be granted based on one of the sets of claims according to a main request filed at the oral proceedings, a first auxiliary request filed with the letter of 27 July 2011, and second to fourth auxiliary requests filed at the oral proceedings.

VI. Independent claims 1, 2, 7 and 8 of the appellants' main request read as follows:

"1. An image processing apparatus comprising:
   a storage unit (36) adapted to store diffusion weighted image data acquired by magnetic resonance imaging;
   a specifying unit adapted to specify a calculation target region in the diffusion weighted image data;
   a calculation unit (45) adapted to calculate at least one of diffusion coefficients and fractional anisotropies, said fractional anisotropies representing indexes of diffusion anisotropy, based on the diffusion weighted image data of the calculation target region; and
a display unit (34) adapted to display the diffusion coefficients and/or the fractional anisotropies calculated by said calculation unit (45), wherein said calculation unit (45) is adapted to perform two-dimensional projection processing of the diffusion coefficients and/or the fractional anisotropies corresponding to the calculation target region, wherein said display unit (34) is adapted to display an image subjected to the two-dimensional projection processing as either of an apparent diffusion coefficient image and a fractional anisotropy image, and wherein said specifying unit is adapted to specify a subset of the diffusion weighted image data which has values beyond a threshold as the calculation target region."

"2. An image processing apparatus comprising: a storage unit (36) adapted to store diffusion weighted image data acquired by magnetic resonance imaging; a specifying unit adapted to specify a calculation target region in the diffusion weighted image data; a calculation unit (45) adapted to calculate at least one of diffusion coefficients and fractional anisotropies, said fractional anisotropies representing indexes of diffusion anisotropy, based on the diffusion weighted image data of the calculation target region; and a display unit (34) adapted to display the diffusion coefficients and/or the fractional anisotropies calculated by said calculation unit (45), wherein said display unit (34) is adapted to display an image subjected to the two-dimensional projection
processing as either of an apparent diffusion coefficient image and a fractional anisotropy image, and wherein said specifying unit is adapted to specify a subset of a projected image which has values beyond a threshold as the calculation target region, the projected image being obtained by projection processing of diffusion weighted volume data."

"7. A magnetic resonance imaging apparatus comprising: a data acquisition unit adapted to acquire diffusion weighted image data; and an image processing apparatus according to any of claims 1 to 6."

"8. An image processing method comprising the steps of: specifying a calculation target region in diffusion weighted image data as a subset of the diffusion weighted image data which has values beyond a threshold; calculating at least one of diffusion coefficients and fractional anisotropies said fractional anisotropies representing an index of diffusion anisotropy, based on the diffusion weighted image data of the calculation target region; and displaying the calculated diffusion coefficients and/or fractional anisotropies, wherein said calculating comprises performing two-dimensional projection processing of the diffusion coefficients and/or the fractional anisotropies corresponding to the calculation target region, and wherein said displaying comprises displaying an image subjected to the two-dimensional projection processing
as either of an apparent diffusion coefficient image and a fractional anisotropy image.”

Claims 3 to 6 are dependent claims.

Independent claims 1, 6 and 7 of the first auxiliary request are identical to claims 1, 7 and 8 of the main request, respectively.

Claims 2 to 5 are dependent claims.

Independent claims 1 and 6 of the second auxiliary request are identical to claims 2 and 7 of the main request, respectively.

Independent claim 7 of the second auxiliary request reads as follows:

"7. An image processing method comprising the steps of:
specifying a calculation target region in a diffusion weighted image data as a subset of a projected image which has values beyond a threshold, the projected image being obtained by projection processing of diffusion weighted volume data;
calculating at least one of diffusion coefficients and fractional anisotropies said fractional anisotropies representing an index of diffusion anisotropy, based on the diffusion weighted image data of the calculation target region; and
displaying the calculated diffusion coefficients and/or fractional anisotropies,
wherein said calculating comprises performing two-dimensional projection processing of the diffusion..."
coefficients and/or the fractional anisotropies corresponding to the calculation target region, and wherein said displaying comprises displaying an image subjected to the two-dimensional projection processing as either of an apparent diffusion coefficient image and a fractional anisotropy image."

Claims 2 to 5 are dependent claims.

Independent claims 1, 6 and 7 of the third auxiliary request read as follows:

"1. An image processing apparatus comprising:
   a storage unit (36) adapted to store diffusion weighted image data acquired by magnetic resonance imaging;
   a specifying unit adapted to specify only a part of the diffusion weighted image data as a calculation target region by excluding image data having values below a threshold from the diffusion weighted image data, so as to reduce interpretation load for a doctor by generating an apparent diffusion coefficient image and/or a fractional anisotropy image selectively from only an area having possibility of cancer, said threshold being set to exclude an area consisting of air or normal tissue;
   a calculation unit (45) adapted to calculate diffusion coefficients and/or fractional anisotropies, said fractional anisotropies representing indexes of diffusion anisotropy, based only on the diffusion weighted image data of the calculation target region, and to perform two-dimensional projection processing of the diffusion coefficients and/or the fractional anisotropies corresponding to the calculation target region; and
a display unit (34) adapted to display an image subjected to the two-dimensional projection processing as the apparent diffusion coefficient image and/or the fractional anisotropy image."

"6. A magnetic resonance imaging apparatus comprising: a data acquisition unit adapted to acquire diffusion weighted image data; and an image processing apparatus according to any of claims 1 to 5."

"7. An image processing method comprising the steps of: specifying a calculation target region as only a part of diffusion weighted image data by excluding image data having values below a threshold from the diffusion weighted image data, so as to reduce interpretation load for a doctor by generating an apparent diffusion coefficient image and/or a fractional anisotropy image selectively from only an area having possibility of cancer, said threshold being set to exclude an area consisting of air or normal tissue; calculating diffusion coefficients and/or fractional anisotropies, said fractional anisotropies representing an index of diffusion anisotropy, based only on the diffusion weighted image data of the calculation target region, and performing two-dimensional projection processing of the diffusion coefficients and/or the fractional anisotropies corresponding to the calculated target region; and displaying an image subjected to the two-dimensional projection processing as the apparent diffusion coefficient image and/or the fractional anisotropy image."
Claims 2 to 5 are dependent claims.

Independent claims 1, 6 and 7 of the fourth auxiliary request differ from the corresponding claims of the third auxiliary request in that for the specifying unit and the corresponding step of specifying the calculation target regions it is more specifically required that "image data having values below a lower threshold and image data having values above an upper threshold" are to be excluded from the diffusion weighted image data, said "lower" threshold being set to exclude an area consisting of air or normal tissue "and said upper threshold being set to exclude fat tissue".

Claims 2 to 5 are dependent claims.

**Reasons for the Decision**

1. In the following reference is made to the provisions of the EPC 2000, which entered into force as of 13 December 2007, unless the former provisions of the EPC 1973 still apply to pending applications.

2. The appeal complies with the requirements of Articles 106 to 108 EPC and Rule 99 EPC and is, therefore, admissible.

3. **Admissibility of the requests**

3.1 The first auxiliary request was filed with the letter of 27 July 2011 and thus slightly more than one month
before the date of the oral proceedings. The main request, the second auxiliary request and the third auxiliary request, which were filed in the oral proceedings, are amended versions of corresponding previous requests that were also filed with the letter of 27 July 2011. The fourth auxiliary request is a new request filed for the first time in the oral proceedings.

All of the present requests were filed in fairly late stages of the appeal proceedings, notably after the oral proceedings had been arranged.

Article 13(1) of the Rules of Procedure of the Boards of Appeal (RPBA) stipulates that "any amendment to a party's case after it has filed its grounds of appeal or reply may be admitted and considered at the Board's discretion. The discretion shall be exercised in view of inter alia the complexity of the new subject-matter submitted, the current state of the proceedings and the need for procedural economy."

Article 13(3) RPBA complements that "amendments sought to be made after oral proceedings have been arranged shall not be admitted if they raise issues which the Board or the other party or parties cannot reasonably be expected to deal with without adjournment of the oral proceedings."

Moreover, the case law of the Boards of Appeal has established a variety of criteria for the admission or rejection of amended claims in appeal proceedings (cf. chapter VII.E.16. of the 6th edition of the "Case Law of the Boards of Appeal of the European Patent
Among these criteria are whether the amendments respond to new objections, whether the amended request is clearly allowable, or whether the need for an additional search arises.

3.2 The main request and the first and second auxiliary requests originate from the first to third auxiliary requests that were filed with the statement of grounds of appeal. The amendments made in writing concern attempts to clarify the claim wording and as such do not significantly change the claimed subject-matter. The further amendments made to the main request and the second auxiliary request in the oral proceedings address a specific objection of lack of clarity and added subject-matter which came up in the discussion at the oral proceedings. Thus, the amendments which resulted in the present main request and the first and second auxiliary requests do not raise issues which were surprising to the Board or which the Board could not be reasonably expected to deal with without adjournment of the oral proceedings. Instead, they merely react to clarity objections with which the appellants were confronted for the first time by the Board's communication that was annexed to the summons to oral proceedings or to a particular objection as to added subject-matter which surfaced in the oral proceedings.

The third auxiliary request, which was filed with the letter of 27 July 2011, has no direct precedent in the requests that were filed with the statement of grounds of appeal. Its subject-matter corresponds however in essence to that of the first auxiliary request. The amendment which was made in the oral proceedings
responds to a clarity objection that was raised by the Board for the first time in the oral proceedings.

For the above reasons, the Board exercised its discretion in favour of the appellants and admitted the main request as well as the first to third auxiliary request into the proceedings.

3.3 The matter is different for the fourth auxiliary request which was filed for the first time in the oral proceedings.

The independent claims of the fourth auxiliary request are based on those of the third auxiliary request and further amended by the additional requirement of excluding from the diffusion weighted image data that data which has values above an upper threshold which is set to exclude fat tissue.

According to the appellants' representative, the amendment served for further distinguishing the claimed subject-matter from the prior art which did not teach to specify a target region of data inside a band between a lower and an upper threshold for the data values. The representative argued in favour of admission of the fourth auxiliary request that the amendment made could not be surprising and must have been foreseen already at the time of the search for relevant prior art because thresholding was claimed already in the originally-filed claims and the corresponding use of a lower and an upper threshold was expounded in detail in the application description as filed.
The Board disagrees. The amendment made to the fourth auxiliary request concerns matter that was at no time claimed in examination and appeal up to the oral proceedings before the Board and for which no search had been made. In fact, the only reference in the originally-filed claims to a threshold is made in original claims 3 and 4 according to which a calculation target region is specified from diffusion weighted image data and/or diffusion weighted volume data "beyond a threshold". Thus there was no reason for extending the search to prior art teachings other than those using a single threshold for establishing a calculation target region. Under these circumstances an admission of the amendments could have necessitated an additional search.

Moreover, although the amendments proposed address objections as to lack of novelty and inventive step they are not occasioned by new objections in this respect which would have arisen for the first time in the appeal proceedings.

Furthermore, the amended claims of the fourth auxiliary request do not appear to be clearly allowable lies because it is doubtful whether the claimed criterion for choosing the upper threshold as "being set to exclude fat tissue" has a clear and unambiguous basis of disclosure in the application documents as originally filed, where it is stated in paragraph [0088] : "For example, on a DWI image, an area having possibility of a cancer shows a high signal compared to an area consisting of a normal tissue. Accordingly, the threshold Th2 for the upper limit is set to a maximum
value which is unable to be shown on a fat tissue or a living body or the like."

For the above reasons, the amendments made to the fourth auxiliary request raise issues which could not be dealt with without adjournment of the oral proceedings, do not respond to fresh objections and are not clearly allowable.

The Board thus did not admit the fourth auxiliary request into the proceedings.

4. Inventive step (Article 52(1) EPC and Article 56 EPC 1973)

4.1 Main request

4.1.1 Document D1 (see in particular the abstract and the chapter "Methods" on page 1235) shows an image processing apparatus which is adapted to store diffusion weighted image (DWI) data that is acquired by magnetic resonance imaging. Postprocessing of this image data includes the calculation of self-diffusion coefficients and their display as diffusion images, eg in the form of maximum intensity projections. The calculation of the self-diffusion coefficients is done on a voxel-by-voxel basis for regions of interest which are selected from the diffusion weighted image data. Thus, the known imaging apparatus comprises, in the terminology of claim 1 of the main request on file, a "storage unit", a "specifying unit" "adapted to specify a calculation target region in the diffusion weighted image data", a "calculation unit" "adapted to calculate at least one of diffusion coefficients and fractional
anisotropies based on DWI data of the calculation target region" and "adapted to perform two-dimensional projection processing of the diffusion coefficients corresponding to the calculation target region", and a "display unit" "adapted to display the diffusion coefficients" and "adapted to display an image subjected to the two-dimensional projection processing" "as an apparent diffusion coefficient image".

D1 is silent as to the manner and means by which the regions of interest for calculating the apparent diffusion coefficient (ADC) values would be selected from the diffusion weighted image data. Thus, document D1 does not show a specifying unit which is adapted to specify the calculation target region as "a subset of the diffusion weighted image data which has values beyond a threshold".

The effect of this feature, ie the objective problem, is to reduce the interpretation load of a doctor to improve diagnostic efficiency (see paragraph [0024] of the published application).

4.1.2 Guidance as to the manner of specifying regions of interest for calculating the apparent diffusion coefficient (ADC) values is provided for instance by each of documents D3 or D4, which both address the task of calculating ADC values on a pixel-by-pixel basis from DWI data.

Document D3 (see the chapters "Introduction" and "Methods") shows an image processing apparatus which produces ADC images from DWI data of the human brain by using an intensity threshold that is provided by image
values which are obtained with magnetic resonance imaging in the absence of a diffusion weighting gradient. The use of this intensity threshold prevents the calculation of the ADC values for areas outside of the brain (such as of air) and as such improves the readability of the ADC images.

Document D4 (see the chapters "Introduction" and "Materials and Methods") shows an image processing apparatus which calculates the ADC values from DWI data of the human brain only for pixels the signal intensity of which is above an automatically determined noise threshold to improve the visibility of lesions on the brain scan.

Thus, each of documents D3 and D4 shows an image processing apparatus having a specifying unit which, in the general terms of claim 1 under consideration, is adapted to specify a calculation target region for the calculation of ADC values as "a subset of the diffusion weighted image data which has values beyond a threshold".

In the Board's view, no exercise of inventive step is required for the skilled person in an attempt to solve the problem referred to above to complement the teaching of document D1 by adopting one of the examples of documents D3 and D4 for the selection of the regions of interest for ADC calculation and thus to arrive at the subject-matter of claim 1 of the main request on file.

This finding applies with equal force to the subject-matter of claims 7 and 8 of the main request.
Claim 7 is directed to an imaging apparatus with a conventional data acquisition unit adapted to acquire DWI data and with an image processing apparatus according to claim 1. Claim 8 defines the functionalities claimed for the various units of the apparatus according to claim 1 as steps of an image processing method.

4.1.3 The subject-matter of claim 2 of the main request differs from that of claim 1 of the main request in that the sequence of the two operations performed by the calculation unit is interchanged. Whereas according to claim 1 the calculation unit first calculates diffusion coefficients and/or fractional anisotropies (FA) for a target region from DWI image data and then performs a two-dimensional projection of the results, the same unit performs according to claim 2 first a projection of the DWI image data and then calculates the diffusion coefficients (ADC) and/or fractional anisotropies (FA).

In both cases the results are the same, ie a two-dimensional image of ADC or FA values for a specified target region. Moreover, no technical effect is apparent which would distinguish the two alternatives. Therefore, although document D1 happens to refer to the variant of performing the projection after having the ADC values calculated, no exercise of inventive skill would by required to choose the alternative manner of operation and thus to arrive at the subject-matter of claim 2 of the main request.
4.1.4 Appellants' arguments

In the appellants' view, the present invention differs from the cited prior art in that an ADC image or FA image was selectively generated from only an area having possibility of cancer. As a result, the amount of information of the originally obtained image data was reduced and a doctor could interpret a projected ADC or FA image with less labour. In that only a part of the obtained image was converted into ADC or FA values the invention was distinguished from the cited prior art which referred to the generation of ADC values corresponding to the entire image obtained. In the present invention, first a step of masking processing (thresholding) was performed on the original DWI data and only then the extracted calculation target region was converted into ADC or FA values. Thus the present invention was capable of significantly reducing the computational load in comparison to the prior art which converted the entirety of the originally obtained DWI data into ADC values and only then performed masking on the converted ADC data.

Moreover, as became apparent in particular from paragraphs [0081], [0090] and [0091] of the description, according to the invention the specifying unit performed the masking operations in a fully automated manner. In distinction thereto, the prior art which dealt with a selection of regions of interest, such as documents D3 and D4, required manual intervention.

In addition, the thresholds indicated in documents D3 and D4 were not comparable to the threshold for
specifying the calculation target region according to the invention. Whereas the present invention was concerned with a threshold allowing for an automated manner of detecting cancer tissue in DWI image data, the prior art according to documents D3 and D4 related to the imaging of ischemic stroke.

4.1.5 These arguments are not convincing for several reasons.

Firstly, they ignore the extent of the teaching provided by the prior art.
From the formulations "From the \( b=0 \) and \( b=1000 \text{ sec/mm}^2 \) images an estimate of apparent self-diffusion coefficients was obtained by first selecting regions of interest …" in document D1, "ADC maps were directly calculated from the two diffusion weighted images. An arbitrary \( b=0 \) intensity threshold was set to prevent the calculation of the ADC in areas outside of the brain" in document D3, and "For ADC calculation only pixel above an automatically determined noise threshold were selected" in document D4, there can be no reasonable doubt that ADC calculation in the cited prior art is performed for only part of the DWI image data in clearly specified calculation target regions.

Secondly, the arguments rely on features or functionalities which are not the subject-matter of the claims on file.
There is nothing in claim 1 of the main request (nor in any other claim of the requests on file) to the effect that the masking operations would be performed in a fully automated manner. Even the appellants' reference to the description cannot support their claim interpretation, given the fact that paragraph [0093]
expressly foresees the setting of appropriate threshold values by a user. Besides, the appellants ignore the fact that according to document D4 the threshold is automatically determined, as is apparent from the above citation. Moreover, there is nothing in claim 1 under consideration which would limit the claimed image processing apparatus to a specific application such as the identification of regions of cancerous tissue.

4.1.6 For the above reasons, the Board arrives at the conclusion that the subject-matter of claim 1 of the appellants' main request is rendered obvious by the teaching of document D1 when combined with any of the teachings of documents D3 and D4.

Consequently, the appellants' main request does not meet the requirement of Article 52(1) EPC and Article 56 EPC 1973 having regard to inventive step and is therefore not allowable.

4.2 First auxiliary request

Since claims 1, 6 and 7 of the first auxiliary request are identical to claims 1, 7 and 8, respectively, of the main request, the respective findings in paragraph 4.1 above of lack of inventive step apply also to the first auxiliary request.

Consequently, the first auxiliary request is not allowable.
4.3 Second auxiliary request

Similarly, the above findings of lack of inventive step apply also to the subject-matter of claim 1 of the second auxiliary request, which is identical to claim 2 of the main request so that the second auxiliary request is not allowable either.

4.4 Third auxiliary request

Claim 1 of the third auxiliary request is based on claim 1 of the main request. It replaces the functional definition of the specifying unit as specifying the calculation target region as a subset of the DWI data having values beyond a threshold, according to claim 1 of the main request, by the equivalent definition that only a part of the DWI data is specified as the calculation target region by excluding image data having values below a threshold.

Moreover, claim 1 of the third auxiliary request additionally indicates the purposes which are intended to be pursued by the specifying of the calculation target region, namely that interpretation load for a doctor is reduced, an ADC and/or FA image is generated selectively from only an area having possibility of cancer, and an area consisting of air or normal tissue is excluded. However, none of these statements of purpose adds substantive matter to the definition of the specifying unit which could further distinguish the claimed subject-matter from what is taught by the prior art according to documents D1, D3 and D4.
Therefore, the subject-matter of claim 1 of the third auxiliary request does not involve an inventive step for basically the same reasons set out above for the subject-matter of claim 1 of the main request.

In consequence, the appellants' third auxiliary request is also not allowable.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar

The Chairman

R. Schumacher

B. Schachenmann