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Datasheet for the decision of 23 June 2015

Case Number: T 2247/11 - 3.2.02

Application Number: 03813604.0

Publication Number: 1571998

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Language of the proceedings: EN

Title of invention:
METHOD AND DEVICE FOR RADIOGRAPHIC IMAGING

Applicant:
EOS Imaging

Headword:

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

Keyword:
Selection of parameters from various lists; added subject-matter - yes (first and first "bis" auxiliary requests)
Added subject-matter - no (first "ter" auxiliary request)
Inventive step - yes (first "ter" auxiliary request)

Decisions cited:

Catchword:

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Case Number: T 2247/11 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 23 June 2015

Appellant: (Applicant)	EOS Imaging 10, rue Mercoeur 75011 Paris (FR)
Representative:	Cabinet Plasseraud 52, rue de la Victoire 75440 Paris Cedex 09 (FR)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 19 May 2011 refusing European patent application No. 03813604.0 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	E. Dufrasne
Members:	M. Stern
	P. L. P. Weber

Summary of Facts and Submissions

I. The applicant lodged an appeal against the decision of the Examining Division refusing European application No. 03 813 604.0. The Examining Division found the various requests then on file not to fulfil the requirements of Article 123(2) EPC and inventive step in view of the following documents:

D1: EP-A-1 168 249
D2: WO-A-02/058 557.

II. Notice of appeal was filed on 20 July 2011 and the fee for appeal was paid the same day. A statement setting out the grounds of appeal was received on 28 September 2011.

III. The Board summoned the appellant to oral proceedings setting out its provisional opinion in an attached communication dated 24 March 2015.

IV. Oral proceedings were held on 23 June 2015.

The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of one of:

- the first auxiliary request filed with letter dated 22 May 2015;
- the first "bis" and first "ter" auxiliary requests filed during the oral proceedings;
- the second to fifth auxiliary requests filed with letter dated 22 May 2015.

The main request filed with letter dated 22 May 2015 was withdrawn.

V. Claim 1 of the ***first auxiliary request*** reads as follows:

"1. Method far radiographic imaging, comprising a step (d) which consists in introducing, into calculation means (17), first digitized radiological data from signals delivered by means (6) of detection of X-rays and corresponding to pixels of a first image of an ananatomical part comprising an osseous body and scanned, in a first incidence, with a beam of X-rays having an energy spectrum distributed about at least two energies, these first data comprising, for each pixel, coordinates of the pixel in the first image and an absorptiometry value for each of said energies, said absorptiometry values being designed to calculate the bone mineral density of the osseous body, referred to a surface area unit, characterized in that it comprises a step (e) which consists in determining the value of a composite index using, on the one hand, first digitized radiological data, and, on the other hand, a three-dimensional actual model of said osseous body,
and in that said composite index is a combination of at least two parameters which comprise the bone mineral density and a parameter chosen from among:
. a specific parameter of the bone geometry, chosen from among the angle, length, surface and volume of an osseous part,
. a mechanical parameter chosen from the section modulus and moments of inertia of an osseous part, and
. a chemical parameter chosen from the water composition, fat composition and bone composition of an anatomical part comprising said osseous body,
and in that a predicted value for a fracture load is deduced from said composite index."

VI. Claim 1 of the ***first "bis" auxiliary request*** reads as follows (amendments to claim 1 of the first auxiliary request are highlighted by the Board):

"1. Method far radiographic imaging, comprising a step (d) which consists in introducing, into calculation means (17), first digitized radiological data from signals delivered by means (6) of detection of X-rays and corresponding to pixels of a first image of an ananatomical part comprising an osseous body and scanned, in a first incidence, with a beam of X-rays having an energy spectrum distributed about at least two energies, these first data comprising, for each pixel, coordinates of the pixel in the first image and an absorptiometry value for each of said energies, said absorptiometry values being designed to calculate the bone mineral density of the osseous body, referred to a surface area unit, characterized in that it comprises a step (e) which consists in determining the value of a composite index using, on the one hand, first digitized radiological data, and, on the other hand, a three-dimensional actual model of said osseous body,
and in that said composite index is a combination of at least two parameters which comprise the bone mineral density and a parameter chosen from among:
. a specific parameter of the bone geometry, chosen from among the angle, length, surface and volume of an osseous part,
. a mechanical parameter chosen from the section modulus and moments of inertia of an osseous part, and
. a chemical parameter chosen from the water composition, fat composition and bone composition of an anatomical part comprising said osseous body,
and in that ~~a predicted value for~~ a fracture risk ~~load~~ is evaluated ~~deduced~~ from said composite index."

VII. Independent claims 1, 17, 22 and 23 of the ***first "ter" auxiliary request*** read as follows (in claim 1, amendments to claim 1 of the first auxiliary request are highlighted by the Board):

"1. Method far radiographic imaging, comprising a step (d) which consists in introducing, into calculation means (17), first digitized radiological data from signals delivered by means (6) of detection of X-rays and corresponding to pixels of a first image of an ananatomical part comprising an osseous body and scanned, in a first incidence, with a beam of X-rays having an energy spectrum distributed about at least two energies, these first data comprising, for each pixel, coordinates of the pixel in the first image and an absorptiometry value for each of said energies, said absorptiometry values being designed to calculate the bone mineral density of the osseous body, referred to a surface area unit, characterized in that it comprises a step (e) which consists in determining the value of a composite index using, on the one hand, said first digitized radiological data, and, on the other hand, a three-dimensional actual model of said osseous body, and in that said composite index is a combination of at least two parameters which comprise the bone mineral density and at least a parameter chosen from among:
. a specific parameter of the bone geometry, chosen from among the angle, length, surface and volume of an osseous part,
~~. a mechanical parameter chosen from the section modulus and moments of inertia of an osseous part, and~~
~~. a chemical parameter chosen from the water composition, fat composition and bone composition of an anatomical part comprising said osseous body,~~
and in that ~~a predicted value for~~ a fracture risk ~~load~~ is evaluated ~~deduced~~ from said composite index."

"17. Device for radiographic imaging, comprising:

- calculation means (17) designed to calculate first digitized radiological data from signals delivered by means (6) of detection of X-rays and corresponding to pixels of a first image of an anatomical part comprising an osseous body and scanned, in a first incidence, with a beam of X-rays having an energy spectrum distributed about at least two energies, these first data comprising, for each pixel, coordinates of the pixel in the first image and an absorptiometry value for each of said energies, said absorptiometry values being designed to calculate the bone mineral density of the osseous body, referred to a surface area unit, and
- storage means for storing at least one three-dimensional actual model of said osseous body,

characterized in that the calculation means (17) are also designed to determine the value of a composite index using, on the one hand, said first digitized radiological data, and, on the other hand, at least one three-dimensional actual model of said osseous body, stored in the storage means,
and in that said composite index is a combination of at least two parameters which comprise the bone mineral density and at least a parameter chosen from among:

. a specific parameter of the bone geometry, chosen from among the angle, length, surface and volume of an osseous part,

and in that a fracture risk is evaluated from said composite index."

"22. Computer program for digital processing of radiographic images, this program executing an operation which consists in calculating first radiological data, from signals delivered by X-ray

detection means (6) and corresponding to pixels of a first image of an anatomical part comprising an osseous body and scanned, in a first incidence, with a beam of X—rays having an energy spectrum distributed about at least two energies, these first data comprising, for each pixel, coordinates of the pixel in the first image and an absorptiometry value for each of said energies, said absorptiometry values being designed to calculate the bone mineral density of the osseous body, referred to a surface area unit, and being
characterized in that it executes an operation which consists in determining the value of a composite index using, on the one hand, said first digitized radiological data, and, on the other hand, a three—dimensional actual model of said osseous body stored in storage means of a computer,
and in that said composite index is a combination of at least two parameters which comprise the bone mineral density and at least a parameter chosen from among:
. a specific parameter of the bone geometry, chosen from among the angle, length, surface and volume of an osseous part,
and in that a fracture risk is evaluated from said composite index."

"23. Computer program product comprising program code means stored on a support readable by a computer, in order to execute the method according to one of Claims 1 to 16, when said program product is operating on a computer."

Claims 2 to 16 and 18 to 21 are dependent claims.

VIII. The arguments by the appellant relevant for the present decision can be summarised as follows:

- Claim 1 of the first and first "bis" auxiliary requests included a definition of the "composite index" defined in original claim 1 which corresponded to some of the alternatives of original claim 17. The supplementary feature of deducing a fracture load found support on original page 22, lines 7 to 9. There was justification for defining the composite index as a combination of the bone mineral density (BMD) with any of the other parameters in original claim 17 due to the prominence of the bone mineral density as a relevant parameter throughout the application as filed. The introduction of the application on pages 1 and 2, in particular page 2, lines 2 to 12, presented the need to calculate BMD in order to evaluate fracture risks. Moreover, page 13, lines 22 to 24 indicated that the composite index included BMD. Page 21, line 8 to page 22, line 9 presented an example of a composite index comprising a combination of various parameters including BMD. It was explained in the paragraph bridging pages 21 and 22 referring to Figures 8 and 9 of the original application that this index correlated better with the fracture load of a bone than BMD alone.

- Claim 1 of the first "ter" auxiliary request no longer defined the composite index in terms of mechanical or chemical parameters, thereby addressing the objections of added subject-matter.

- The invention claimed in the first "ter" auxiliary request was not rendered obvious by D2, neither alone nor in combination with D1, for the following reasons. The "composite index" as claimed was a single-value index combining two or more different parameters from which fracture risk was evaluated, whilst in D2 fracture risk was evaluated separately for different parameters. It was not disclosed or suggested in D2 to combine a plurality of parameters to obtain a relevant single index to directly assess fracture risk. Moreover, D2 did not disclose or suggest to include BMD in this parameter combination. The composite index was shown in Figure 8 to efficiently and precisely assess fracture risk, in particular with a better correlation than that of BMD alone shown in original Figure 9 (which in the original text is referred to as Figure 7). Also D1 did not disclose to determine a composite index defined as a *combination* of at least two parameters. In fact, D1 disclosed to calculate clinical indices related to the geometry *or* to the composition or density of the objects examined.

Reasons for the Decision

1. The appeal is admissible.

2. The invention concerns a dual-energy X-ray absorptiometry method and device for obtaining, firstly, a three-dimensional representation of the bone mineral density (BMD) of the osseous body (page 1, lines 10 to 28; page 2, lines 5 to 12), and for determining, in addition, the value of a "composite index" using the digitised radiological data and a three-dimensional model of the examined bone (page 2, lines 19 to 31). This composite index allows the evaluation of fracture risks (page 2, lines 2 to 5 and 34 to 38).

3. First and first "bis" auxiliary requests - Article 123(2) EPC

3.1 Claim 1 (of both requests) includes a definition of the "composite index" recited in original claim 1 which, according to the appellant, corresponds to some of the alternatives included in or covered by original dependent claim 17. The definition of the "composite index" is the following (amendments to original claim 17 are highlighted by the Board):

"~~the~~ <u>said</u> composite index is <u>a combination of at least two parameters which comprise the bone mineral density and</u> a parameter chosen from among<u>:</u>
. [a] a specific parameter of the bone geometry, chosen from among the angle, length, surface and volume of an osseous part,
~~. [b] a physical parameter chosen from the bone mineral density and the mass of an osseous part,~~
. [c] a mechanical parameter chosen from the section modulus and moments of inertia of an osseous part, and
. [d] a chemical parameter chosen from the water composition, fat composition and bone composition of an anatomical part comprising said osseous body,
~~. or any combination of at least two of the preceding parameters~~".

In original claim 17 the "composite index" was defined in general terms as a combination of two (or more) parameters chosen from four lists of different parameters. In current claim 1, instead, the "composite index" is defined as a more specific combination of a particular paramenter - the bone mineral density (BMD) - selected from one of the lists (list [b]) with one (or more) of the parameters from the other three lists [a], [c] and [d].

The question therefore arises whether there is a basis for this selection in the application as filed.

3.2 The appellant was of the opinion that the prominence of BMD as a highly relevant parameter throughout the application justified its selection in combination with any of the parameters of the three lists [a], [c] and [d].

The Board disagrees. As explained under point 2 above, the method of the present invention is aimed at obtaining a three-dimensional representation of the BMD of the osseous body, and, *in addition*, at determining the value of a "composite index" (page 1, lines 10 to 22 and page 2, lines 19 to 25; original claim 1). Hence, the original application presents the determination of both the BMD and the composite index as two essential evaluations performed by the method of the invention. Accordingly, from the disclosed relevance of BMD, the skilled person would not deduce that original claim 17 disclosed the selection of BMD (from list [b]) in combination with one (or more) of the parameters of the three lists [a], [c] and [d].

3.3 The appellant pointed also to passages in the original descripton which disclosed examples of a composite index including BMD.

The Board agrees that in the cited passages (on page 13, lines 22 to 24; and on page 21, line 8 to page 22, line 9) examples of a composite index including BMD are presented. According to the first passage, the composite index is determined from BMD referred to a bone volume. In the second passage, the composite index is defined as a mathematical linear combination of BMD, femoral head diameter D, midneck cross section area S and neck-shaft angle X. The latter composite index was moreover shown in Figure 8 to have a better correlation with fracture load than BMD alone (paragraph bridging pages 21 and 22).

In both examples, BMD is combined with bone-geometry parameters. The Board therefore considers that these examples provide a clear pointer to the selection of BMD (from list [b]) in combination with one (or more) of the bone-geometry parameters of list [a] of original claim 17. The Board does not consider, however, that these (geometry-based) examples also provide a pointer for the combined selection of BMD with one or more parameters of the (entirely different) mechanical and chemical parameters of lists [c] and [d]. Thus, although conceptually encompassed by original claim 17, this selection does not emerge clearly and unambiguously from the content of the original application as a whole.

3.4 The Board consequently concludes that claim 1 of the first and first "bis" auxiliary requests contains subject-matter extending beyond the content of the application as filed, contrary to the requirements of Article 123(2) EPC.

4. First "ter" auxiliary request

4.1 Claim 1 of this request defines the composite index as a combination of BMD with one (or more) of the bone-geometry parameters of list [a]. For the reasons given above, in particular under point 3.3, claim 1 satisfies the requirements of Article 123(2) EPC.

4.2 Inventive step

4.2.1 The appellant agrees that the closest prior-art document is D2, disclosing a dual-energy X-ray absorptiometry method designed to calculate bone mineral density as defined in the preamble of claim 1 (paragraphs [0026], [0151] and [0152]; step 660 in the flow chart of Figure 6A).

As shown at the end of the flow chart of Figure 6A, after a three-dimensional actual model of the osseous body is obtained in step 690, also a risk of injury index is calculated (in step 698; paragraphs [0156] to [0158]). The value of the risk of injury index is thus determined using the "first digitized radiological data" and the "three-dimensional actual model of said osseous body" as defined in claim 1. D2 discloses in paragraph [0157] examples of estimates for the risk of injury (e.g. fracture risk), such as estimates of mechanical strength and the determination of the spatial relationship between bones and metal objects implanted in the patient.

4.2.2 D2 does not disclose, however, to determine the value of a composite index as defined in the characterising portion of claim 1, in which the composite index is a combination of at least two parameters which comprise the bone mineral density and at least a parameter of the bone geometry chosen from among the angle, length, surface and volume of an osseous part. Consequently, the method of claim 1 is novel over D2.

4.2.3 The application provides convincing evidence that the value of a composite index including BMD and several bone-geometry parameters as disclosed on page 21, lines 17 to 32 has a better correlation with fracture load than BMD alone (paragraph bridging pages 21 and 22).

4.2.4 The objective technical problem arising from the mentioned differentiating features of claim 1 is to improve the evaluation of fracture risks, as formulated in the original application on page 2, lines 2 to 5 and 34 to 38.

4.2.5 Rather than evaluating fracture risk from just a single parameter or evaluating different fracture risks from different parameters, as in D2, the claimed method allows the evaluation of fracture risk from the single value of a composite index which combines two or more relevant parameters. D2 does not disclose or suggest to combine a plurality of parameters to obtain a relevant single index to directly assess fracture risk. The claimed composite index makes it possible to efficiently and precisely assess fracture risk, in particular with a better correlation than that of BMD alone (point 4.2.3 above).

4.2.6 Document D1 discloses a three-dimensional X-ray examination method which calculates clinical indices based on either the geometry or the BMD of the examined objects (paragraph [0049]). D1 however fails to disclose the calculation of a single value of an index which combines these parameters, i.e. a composite index in the sense of claim 1. Therefore, from the combination of D2 with D1, the skilled person would not arrive at the claimed subject-matter.

4.2.7 Consequently, the method of claim 1 is not rendered obvious by the prior art on file.

Independent claims 17, 22 and 23 define, respectively, an apparatus, a computer program and a computer program product comprising the corresponding features of claim 1. Hence, also the subject-matter of these independent claims is non-obvious over the available prior art.

It follows that the subject-matter of the aforementioned independent claims of the first "ter" auxiliary request involves an inventive step within the meaning of Article 56 EPC. This applies a fortiori to the preferred embodiments defined in dependent claims 2 to 16 and 18 to 21.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance with the order to grant a patent on the basis of the first "ter" auxiliary request:
   - claims 1 to 23;
   - pages 1 to 27 of the adapted description; and
   - adapted figures 1 to 10

   all filed during oral proceedings.

The Registrar: The Chairman:

D. Hampe E. Dufrasne

Decision electronically authenticated