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D E C I S I O N
of 22 February 2002

Case Number: T 1082/99 - 3.2.2

Application Number: 95120150.8

Publication Number: 0719520

IPC: A61B 8/08

Language of the proceedings: EN

Title of invention:

Method and apparatus for measuring speed of sound in tissue

Applicant:

Aloka Co. Ltd.

Opponent:

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Headword:

-

Relevant legal provisions:

EPC Art. 52(1), 56

Keyword:

"Inventive step (yes, after amendment)"

Decisions cited:

-

Catchword:

-



Case Number: T 1082/99 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 22 February 2002

Appellant: Aloka Co. Ltd.
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Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 17 August 1999
refusing European patent application
No. 95 120 150.8 pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: W. D. Weiß
Members: S. S. Chowdhury
U. Tronser

Summary of Facts and Submissions

I. This appeal is against the decision of the examining division dated 17 August 1999 to refuse European patent application No. 95 120 150.8

The ground of refusal was that, having regard to the following documents, the subject-matter of all claims of the main request and first to fourth auxiliary requests lacked inventive step:

D1: EP-A-0 576 217,

D2: US-A-5 343 863.

The examining division argued that claim 1 of all requests lacked inventive step since, starting from the closest prior art document D1, it would be obvious to measure, in a preparing step, the propagation time of ultrasound between two transducers with the transducer units pressed together under a predetermined pressure, since it was clear that the spurious time of flight through contact pads of the transducers must be eliminated. Another distinguishing feature of claim 1, that the transducer cover is deformable, was obvious since it would be used for reasons of hygiene.

Other grounds of refusal were that independent device claim 17 of the main and second auxiliary requests was not linked together with any of the method claims 1 to 9 by a single common inventive concept as required by Article 82 and Rule 30 EPC, and that the claims of the first auxiliary request lacked clarity since there was a contradiction between claims 1 and 9.

II. On 18 October 1999 the appellant (applicant) lodged an appeal against the decision and paid the prescribed fee. On 23 November 1999 a statement of grounds of appeal was filed.

III. Following a telephone consultation between the appellant's representative and the rapporteur the appellant filed new claims and description pages.

IV. The appellant requests that the decision under appeal be set aside and that a patent be granted on the basis of the following documents:

- Claims 1 to 9 filed by letter dated 22 January 2002.
- Description pages 2 and 5 to 7 and 9 filed by letter dated 22 January 2002.
- Description pages 3 and 4 filed by telefax dated 25 January 2002.
- Drawing Figures 1 and 3 to 8 as originally filed.
- Drawing Figure 2 filed by telefax dated 25 January 2002.

V. Independent claims 1 and 9 read as follows:

"1. A method for measuring the speed of sound in tissue wherein a tissue (70) is held between a pair of transducer units (10a, 10b), ultrasound is transmitted and received by said units (10a, 10b), and each of said units (10a, 10b) comprises an ultrasonic transducer (12a, 12b), a transducer cover (14a, 14b) of which at

least part deforms freely and which covers said ultrasonic transducer (12a, 12b), and a liquid acoustic matching material (16a, 16b) filling the space between said cover (14a, 14b) and said transducer (12a, 12b), said method comprising the steps below:

a) a preparing step wherein the covers (14a, 14b) of the transducers (12a, 12b) of said pair of transducer units (10a, 10b) are pressed together under a predetermined pressure, ultrasound is transmitted and received, and the propagation time of said ultrasound from one to the other of said transducers (12a, 12b) is measured;

b) a measuring step wherein a tissue (70) is held between said pair of transducer units (10a, 10b) under said predetermined pressure, ultrasound is transmitted and received, and the propagation time of said ultrasound from one to the other of said transducers (12a, 12b) is measured, and the distance between said transducers (12a, 12b) is measured; and

c) a calculating step wherein the speed of sound in said tissue is computed based on the propagation time measured in said preparing step, and on the propagation time and distance between said ultrasonic transducers (12a, 12b) measured in said measuring step."

"9. A tissue assessment apparatus for computing assessment values of tissue based on a received signal obtained when ultrasound is passed through a tissue and received, said apparatus comprising: a pair of transducer units (10a, 10b) wherein each of said units comprises a transducer (12a, 12b), a transducer cover (14a, 14b) of which at least part deforms freely and

which covers said transducer (12a, 12b), and a liquid acoustic matching material (16a, 16b) filling the space between said cover (14a, 14b) and said transducer (12a, 12b), a transducer unit moving mechanism (24a, 24b, 30, 34) for moving said pair of transducer units (10a, 10b) closer together, so that the covers (14a, 14b) can be pressed against each other, or further apart, a torque limiter (32) for providing the same limiting force with which said transducer units (10a, 10b) press against said tissue (70) and against each other when said tissue (70) is held between said pair of transducer units (10a, 10b), and when no tissue is held therebetween, respectively, a memory (60), means for storing in said memory (60) a propagation time of ultrasound between said transducers (12a, 12b) when the transducer covers (14a, 14b) of said pair of transducer units (10a, 10b) are pressed to each other with a predetermined force, a time measuring device (54) for measuring the propagation time of ultrasound between said transducers (12a, 12b) based on a received signal from said transducer units (10a, 10b), a distance measuring device (56) for measuring the distance between said transducer units (10a, 10b), and a processor (58) for computing the speed of sound in said tissue (70) based on the propagation time stored in said memory (60), the propagation time found by said time measuring device (54), and the distance measured by said distance measuring device (56)."

Claims 2 to 8 are dependent on claim 1.

VI. The appellant argued as follows:

Document D1 did not teach the step of determining the transit time through the contact pads before each

measuring step, it only taught performing a correction of the measurement by using a fixed value for this time. The problem posed in the application was itself inventive since it sought not only to eliminate errors arising from different deformations of the silicone pads, but also errors from environmental conditions such as the temperature.

Reasons for the Decision

1. The appeal is admissible since it complies with the provisions mentioned in Rule 65(1) EPC.

2. *Amendments*
 - 2.1 Claim 1 and claim 9 of the new claims differ from respective claims 1 and 17 as originally filed in that they specify that the acoustic matching material is a liquid and that it is the covers of the transducers rather than the transducers themselves that are pressed together. The first of these features is supported by column 5, lines 55 to 58, of the A2 publication, for example, and the second one by Figure 4, for example.

Claim 9 includes the further feature that the torque limiter provides the same limiting force with and without tissue between the transducers, which feature is supported by column 7, lines 33 to 50 of the A2 publication.

Dependent claims 2 to 8 correspond to claims 2 to 8 as originally filed. The description has been amended for consistency with the new claims, in particular Embodiment 3 has been cancelled. Therefore, there is no

objection to the claims or the description under Article 123(2) EPC.

3. *Novelty*

This has not been an issue during the examination procedure and the Board sees no reason to investigate it.

4. *Inventive step*

4.1 Background art

The patent application is based on tissue assessment apparatus known from Japanese Patent No. HEI-7-204205 wherein the fronts of two ultrasonic transducers are covered with a freely deformable cover filled with an acoustic matching material, and the covers are brought into contact with a sample and the propagation time of the ultrasound between the transducers is measured. The advantage of such a freely deformable cover is that it conforms easily to the surface of the sample, so no air layer is present between the transducers and the sample.

4.2 The technical problem

The following problems, inter alia, are identified in the application, as set out in column 2 of the A2 publication:

- If an air pocket forms in the acoustic matching material in the cover, then if the atmospheric pressure of the measuring environment changes, the air pocket expands or contracts and the

deformation of the cover and the average thickness of the acoustic matching material therefore changes.

- The thickness of the acoustic matching material changes if the material leaks out of the cover due to long periods of use.
- If the cover is used for long periods its flexibility and the degree to which it is deformed changes, which also causes the thickness of the acoustic matching material to vary.

The above problems lead to errors in the measured result for the speed of sound and the object of the invention to obviate the above problems.

4.3 The solution

To solve the above problems the method of claim 1 has the following features that combine together to meet the object of the invention:

- (a) In a preparing step the transducers are pressed together under a predetermined pressure and the propagation time of ultrasound is measured.
- (b) In a measuring step tissue is held between the transducers under the same predetermined pressure and the propagation time of ultrasound is measured.
- (c) In a calculating step the speed of sound in the tissue is computed based on the propagation time measured in the preparing step and the measuring

step.

4.4 The closest prior art

In view of the foregoing considerations the closest prior art document must be one that describes apparatus having ultrasonic transducers that are covered with a freely deformable cover filled with an acoustic matching liquid, since it is only in this class of apparatus that the above listed problems arise.

Document D1 does not relate to such apparatus in that it has front silicone pads for acoustic matching but no liquid-filled freely deformable cover, so that the above problems would not occur in this apparatus. Therefore, this is not the closest prior art document.

Of the documents cited in the application and in the European Search Report only Japanese Patent No. HEI-7-204205 discloses apparatus of the class under consideration, ie a transducer with a freely deformable cover and an acoustic matching liquid filling the space between the cover and the transducer, and this document is the closest prior art document, accordingly.

4.5 This document discloses tissue assessment apparatus including ultrasonic transducers with the freely deformable covers enclosing an acoustic matching liquid. A tissue is gripped between the ultrasonic transducers and the propagation time of the ultrasound between the both transducers is measured. The propagation speed of the ultrasound in the tissue is found by dividing the distance between the transducers by the propagation time.

- 4.6 The applicant has identified the above-mentioned technical problems, which are not known in the prior art and this is already an indication of inventive activity. That the method of claim 1 involves an inventive step is confirmed by the fact that the prior art also does not disclose or suggest any solution to the above problems.
- 4.7 Document D1 discloses an apparatus and method for measuring the speed of sound in tissue by measuring the distance between two transducers and the time of flight of ultrasound between the transducers with tissue (a foot) placed therebetween. According to the examining division the preparing step in which the transducers are pressed together under a predetermined pressure and the propagation time of ultrasound is measured, and the measuring step in which tissue is held between the transducers under the same predetermined pressure and the propagation time of ultrasound is measured, are rendered obvious by the disclosure of document D1.

This argument is wrong for, while the spurious effect of the time of flight of ultrasound through the matching material must, indeed, be allowed for, document D1 does not suggest the steps (a) and (b) of the claimed method for the following reasons:

Firstly, it must be noted that the use of a freely deformable cover as well as the two steps (a) and (b) must be considered in combination since it is the combination of these features that solves the above problems. An important point is that the transducer covers are pressed to each other as well as to the tissue, in steps (a) and (b) with the same predetermined pressure, the purpose of which, as

explained in column 7, lines 33 to 50, is to subject the covers and the matching material to the same deformation and thickness in the two steps. With the same distortion in the two steps, any effects of air pockets, leakage, environmental changes, etc would be the same in the two steps and hence result in a better cancellation of the effect on the propagation time, which would clearly improve the accuracy of compensation and solve the technical problems set out above.

Document D1 describes transducers having front silicone contact pads in which, as stated above, the problems of the application do not arise. Moreover, the shape of the contact pads is variant only to the extent that they are slightly and gently compressed (see column 6, lines 37 to 56). Therefore, a method of compensating for the ultrasound transit time through the pads involving a simple "algorithm", as described at the end of this document, would suffice. Such an algorithm could be, for example, a calculated value or a value calibrated in the factory, both of which values could be stored in a computer memory, for example as described in document D2 with respect to the sound transit time through a reference material, see point 4.9, below. There is no need for any more elaborate method here.

Secondly, for compensating for the transit time of sound through the silicone pads, document D1 only mentions the use of an algorithm (column 11, lines 24 to 26) and not the step of pressing the transducers together. The term "algorithm" implies the use of a fixed value in a subtraction step and not a dynamic one in the sense that it involves an operation on the

transducers so to allow for environmental changes from time to time. Moreover, the algorithm does not describe any specific procedure and this vague sentence does not suggest the specific steps (a) and (b) of claim 1, as the examining division argues.

This view is supported by the fact that whereas the transit time of sound through soft tissue is compensated by actually measuring it, as described in detail with reference to Figures 13 to 18 (in particular see column 9, lines 38 to 43 and column 10, lines 55 to 57), that through the silicone pads is hardly described at all, and when it is briefly described, at the end of the description, it is by using quite different terminology ("automatically normalised within the system algorithm").

- 4.8 As discussed in point 4.7 above, it is not permissible to take the features of the claims in isolation and to dismiss each one of itself as being obvious. The examining division took feature a) of claim 1 in isolation and dismissed it as being an obvious option readily available to the person skilled in the art, but this is an argument made with hindsight since it de-links the combined effect of this step from step (b) of the claim.

Similarly, the argument that although document D1 does not disclose a deformable cover, the use of one for hygiene reasons would be obvious, is wrong for the same reason, that this feature is being taken in isolation. It is important, in order to exclude the use of hindsight, to analyse the problems that a freely deformable cover causes (see point 4.2 above) and its effect in the steps (a) and (b) of claim 1 (see

point 4.1 above). In the application the freely deformable cover is used is for a reason completely unrelated to hygiene, viz. to contain an acoustic matching liquid and to conform closely to a body part.

To summarise, document D1 neither discloses nor suggests the use of a freely deformable cover or the steps (a) and (b) of claim 1, either singly or in combination.

- 4.9 Document D2 also fails to disclose a transducer with a freely deformable cover enclosing a liquid acoustic matching material, or the steps (a) and (b) of claim 1.

This document describes an ultrasound densitometer for measuring the integrity of bone, etc. wherein transducers having both a contact pad and coupling gel are fixed a given distance apart and the transit time or the attenuation of acoustic signals through the bone is measured. The measured values are compared with corresponding values obtained either by performing measurements on a standard material or by comparison with values stored in a database. The latter process is referred to as a calibration in column 19, lines 11 to 21, but might equally be referred to as an algorithm. There is no mention of allowing for the transit time through the contact pads or the gel. This document also does not disclose the steps (a) and (b) of claim 1.

- 4.10 The examining division dismissed the feature (a) as something the skilled person would naturally consider given the lack of choice available in this respect. This argument was also made with the benefit of hindsight since the prior art, as seen above, gives various ways of compensating for time of flight through

tissue and contact pads, but not that defined in step (a) of claim 1.

- 4.11 Therefore, an evaluation of the present problem and solution leads to the conclusion that the method of claim 1 is not an obvious development of prior art methods.
- 4.12 The apparatus of claim 9 has special features for carrying out the method of claim 1, including transducer units with freely deformable covers enclosing a liquid acoustic matching material. A torque limiter is provided for limiting the pressure to the same value during both the steps (a) and (b) of claim 1. Again, starting from Japanese Patent No. HEI-7-204205 as the closest prior art document, there is no incentive in the prior art for adding a torque limiter to the apparatus of this document.

The purpose of the torque limiter in document D1 is so that the silicone pads will bear against the patient with the same pressure from one measurement to the next or from one patient to another (column 2, lines 36 to 46 and column 6, line 51 to column 7, line 3), so as to provide the same compression regardless of the size of the body part. The torque limiter of this document is not for providing the same deformation of a freely deformable cover in the two cases, with and without a body part therebetween. Therefore, the apparatus of claim 9 also involves an inventive step.

5. *Other objections*

Unity of invention: It will be seen from point 4.10 above that the subject-matter of independent claims 1

and 9 both involve an inventive step for the same reason, that they define ultrasonic transducers with a freely deformable cover enclosing a liquid acoustic matching material, and the steps (a) and (b) of claim 1 or the means for carrying out these steps. Therefore, they relate to a single general inventive concept and fulfil the requirement of Article 82 EPC.

Clarity: The inconsistency that the examining division noted between claims 1 and 9 has been resolved by cancelling claim 9, relating to Embodiment 3, and this embodiment has also been cancelled.

6. For the above reasons the application meets the requirements of the EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the first instance to grant a patent on the basis of the main request according to paragraph IV. of the "Summary of Facts and Submissions".

The Registrar:

The Chairman:

V. Commare

W. D. Weiß