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D E C I S I O N
of 2 July 2001

Case Number: T 0199/97 - 3.2.2

Application Number: 91104677.9

Publication Number: 0449179

IPC: A61B 17/22

Language of the proceedings: EN

Title of invention:

Shockwave generating system capable of displaying shockwave effective region

Applicant:

KABUSHIKI KAISHA TOSHIBA

Opponent:

-

Headword:

-

Relevant legal provisions:

EPC Art. 56

Keyword:

"Inventive step (yes) - after amendment"

Decisions cited:

-

Catchword:

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Boards of Appeal

Chambres de recours

Case Number: T 0199/97 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 2 July 2001

Appellant: KABUSHIKI KAISHA TOSHIBA
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Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 28 October 1996
refusing European patent application
No. 91 104 677.9 pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: W. D. Weiß
Members: S. S. Chowdhury
R. T. Menapace

Summary of Facts and Submissions

I. This appeal is against the decision of the examining division dated 28 October 1996 to refuse European patent application No. 91 104 677.9.

The ground of refusal was that, having regard to the following documents, the subject-matter of claim 1 of the main request lacked inventive step:

D1: WO-A-8 701 927

D3: DE-U-8 715 902

The Board of Appeal has also considered the following document:

D5: Biliary Lithotripsy, (Ferrucci et.al.) Year Book Medical Publishers, Inc., 1989, pages 253 to 263.

The examining division argued that, starting from the closest prior art document D3, it would be obvious that an indication of the second dimension was missing in the display of this document and that choosing a pattern that substantially surrounds an area or contour was then the most straightforward design measure which the person skilled in the art would readily envisage for an improved representation of the shockwave effective region.

The examining division also stated in the decision that claim 1 of the auxiliary request was allowable. It appears from the minutes of the oral proceedings before the examining division, however, that in addition to the main and first auxiliary requests, two further

requests were filed, both bearing the heading "Auxiliary request II", and it was the second of these requests that was considered allowable.

II. On 27 December 1996 the appellant (applicant) lodged an appeal against the decision and paid the prescribed fee. On 13 February 1997 a statement of grounds of appeal was filed.

III. Following a telephone consultation between the appellant's representative and the rapporteur on 8 January 2001 and a communication dated 21 March 2001, the appellant filed new claims and description pages as main and auxiliary requests.

IV. The appellant requests that the decision under appeal be set aside and that a patent be granted on the basis of one of these requests. The main request comprises claims 1 to 12 and description pages 1 to 3, 3a, and 4 to 18 filed with letter dated 8 June 2001, and the originally filed drawings.

V. Independent claims 1 and 2 of the main request read as follows:

1. "A shockwave generating apparatus comprising

imaging means (3, 20, 40) for producing an image of an interior area of a biological body (B0) under medical examination, said biological body (B0) containing an object (9) to be destroyed;

shockwave generating means (12, 50) for generating and transmitting a shock wave (26) to be focused onto said object (9) to be destroyed;

positioning means (60) for setting the focus position (30) of the shockwave (26) with respect to the image of said interior area; and

means (90, 100) for controlling operation of said positioning means (60) for setting the focus position (30),

characterized by further comprising

storage means (46) for storing predetermined data on a shockwave effective region (Eh) prepared in advance on the basis of experimental results, said shockwave effective region (Eh) indicating a region where the shockwaves (26) may influence said biological body (BO);

pattern producing means for producing a shockwave effective region pattern (M_1 - M_7 , M_{11} - M_{13}), said shockwave effective region pattern substantially surrounding a contour of said shockwave effective region (Eh); and

display means (80) for displaying a superimposed image of the image of said interior area and the shockwave effective region pattern."

2. "A hyperthermia generating apparatus comprising

imaging means (3, 20, 40) for producing an image of an interior area of a biological body (BO) under medical examination, said biological body (BO) containing an object (9) to be destroyed;

continuous ultrasonic wave generating means (12, 50) for generating a continuous ultrasonic wave (26) to be

focused onto said object (9) to be destroyed;

positioning means (60) for setting the focus position (30) of the ultrasonic wave (26) with respect to the image of said interior area; and

means (90, 100) for controlling operation of said positioning means (60) for setting the focus position (30),

characterized by further comprising

storage means (46) for storing predetermined data on a thermal effective region (Eh) prepared in advance on the basis of experimental results, said thermal effective region (Eh) indicating a region where the ultrasonic wave (26) may influence said biological body (B0);

pattern producing means for producing a thermal effective region pattern (M_1 - M_7 , M_{11} - M_{13}), said thermal effective region pattern substantially surrounding a contour of said thermal effective region (Eh); and

display means (80) for displaying a superimposed image of the image of said interior area and the thermal effective region pattern."

Claims 3 to 12 are dependent on these claims.

VI. With respect to claim 1 the appellant argued as follows:

The expression "prepared in advance on the basis of experimental results" in claim 1 was clear since it

characterised the shockwave data so as to distinguish it from estimated data.

The claimed apparatus had a display with several distinct advantages, one of which was that the biological image displayed within the contour surrounding pattern was unobstructed, so an operator could adjust the shockwave generator in a precise manner. Another was that the operator could purposefully move the center of the shockwave effective region about the object to be destroyed without affecting adjacent tissue.

The document D3 merely taught to display a line whose length may characterise a possible effect area, but it did not teach displaying a shockwave effective region pattern surrounding a contour of a shockwave effective region, and hence a two-dimensional indication in which the image inside was displayed.

Reasons for the Decision

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

The main request

2. *Amendments*

- 2.1. Claim 1 includes the following features not contained in claim 1 of the application as originally filed [emphasis in bold added]:

(a) The biological body contains an object to be

destroyed

(b) Positioning means for setting the focus position of the shock waves and means for controlling operation of said positioning means for setting the focus position.

(c) Storage means store predetermined data on a shockwave effective region **prepared in advance on the basis of experimental results**

(d) Pattern producing means produce a shockwave effective region pattern that substantially surrounds a contour of the shockwave effective region.

Other features (e.g. positioning means.....) have been reworded without materially affecting their scope.

2.2. The new features of claim 1 are allowable under Article 123(2) EPC since they are supported by the application as originally filed as follows:

(a) Medical apparatus employing shockwaves are normally used to destroy kidney stones, tumours, etc., and Figure 4 shows shock waves 26 focussed onto a renal calculus 9, the intention obviously being to fragment it. The term "destroyed", therefore, more accurately describes the purpose of the apparatus than the original one ("cured") and is justified by the original disclosure, see for example the first sentence of the description, which talks of "disintegration" of an object by shockwaves.

(b) This feature is described in the paragraph linking

columns 6 and 7 of EP-A-0 449 179 and in the paragraph linking columns 8 and 9, with reference to Figure 1, where there is described that the position controller 60 is used to control the position of the transducer 12, and in turn is controlled by the system controller 100.

- (c) The shockwave effective region is determined by measurement, as described under "Generation of Effective Region Pattern M_1 " in column 6 of EP-A-0 449 179, and in column 8, lines 32 to 35. These passages provide support for this feature.
- (d) This feature finds support in original claims 5 and 7 and in Figures 3 and 5.

2.3. The same considerations apply to claim 2. The dependent claims and are equally supported by the application as originally filed, their subject-matter being derivable from the original dependent claims. The description corresponds to the description as originally filed but with minor amendment and a review of the relevant prior art.

Therefore, there is no objection to the claims and description under Article 123(2) EPC.

3. *Clarity*

The examining division had objected to the expression "prepared in advance on the basis of experimental results", in claim 1, in that it relates to a process of data acquisition rather than to constructional features that characterise the claimed apparatus. While this statement is correct, it is not objectionable in claim 1 for the following reasons:

Claim 1 defines display means for displaying a superimposed image of the interior area of a biological body and the shockwave effective region pattern, which has a certain size, this size being determined by data stored in storage means. These are all constructional features to which there is no objection. The claim further clarifies how the data are obtained by use of the above expression, which while not being a constructional feature, supplements the other constructional features, and is not necessarily unclear in the context of the claim. For example, the **measured** intensity profile, size, and position of the focal spot may differ from **calculated** ones owing to diffraction effects. The above expression clarifies how the data are obtained and, therefore, has a bearing on the actual size of the pattern on the display.

Were this expression to define the solitary novelty invoking feature it might be questionable, but it is not, it merely supplements other constructional features. Therefore, the claim as a whole is clear in this respect.

4. *Novelty*

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

5. *Inventive step*

5.1. The prior art

Both of the documents D1 and D3 disclose a shockwave generating apparatus comprising imaging means for producing an image of an interior area of a biological body under medical examination, the biological body containing an object to be destroyed; shockwave generating means for

generating and transmitting shockwaves to be focused onto the object to be destroyed; positioning means for setting the focus position of the shockwaves with respect to the image of said interior area; and means for controlling operation of said positioning means for setting the focus position.

5.2. The technical problem

The problem to be solved is set out in the first two paragraphs on page 3 of the application as originally filed. This may be summarised as follows: The destructive effect of a shock wave is not confined to the focal spot, but extends to a finite volume around this spot, called the "effective region". The size of this region depends on the strength of the waves, the geometry of the wave-producing transducer, etc.

In the prior art, if the focal point marker is positioned at the end of an object to be treated, or if the effective region is larger than the object to be destroyed, then the effects of the shockwaves may spill over into healthy tissue around the object and cause damage there. Accordingly, the object of the invention is to provide a safe shockwave generating apparatus that avoids the potentially damaging effects of shockwaves in healthy tissue around the object to be destroyed.

It was generally known that shockwaves must be focussed so that the focal region lies within the object to be treated (see document D5, page 256, right column, fourth complete paragraph), but the problem of the shockwaves intended to destroy an object accidentally also damaging surrounding tissue is not disclosed in the available documents, and by itself is already indicative of inventive activity.

In its communication dated 24 May 1995 (points 3.2 of the communication), the examining division defined the technical problem as being "displaying an improved representation of the shock-wave effective region". This technical problem is too general since it does not take into account the objective achievement of the claimed apparatus over the prior art. This achievement lies not just in providing an improved display but in providing an improved display to a given purpose, i.e. to minimise harm to surrounding tissue.

5.3 The solution

To solve the above problem the claimed apparatus has features defined in the characterising part of claim 1. Each of these features contributes to solving the problem of the invention as follows:

- (i) The shockwave effective region is defined after measurement, as described under "Generation of Effective Region Pattern M_1 " starting on page 8 of the application as originally filed. This feature defines a region outside which the waves in the focal spot will not influence (damage) surrounding tissue.
- (ii) This feature provides a well determined shockwave effective region pattern which is displayed superimposed on the biological body, and outside which no damage to tissue will occur, as explained on page 10, lines 8 to 15.
- (iii) This feature provides an overlapping display in which the shockwave effective region pattern is shown as a pattern surrounding the contour of the shockwave effective region, and since it is the former that is

displayed and not the latter, the display will feature the shockwave effective region pattern superimposed on the object to be treated but not obstructing it, so that the operator will be able to see clearly whether or not the shockwave effective region pattern is confined to be wholly within the object or spills over into surrounding tissue. The latter situation can then be easily avoided.

These three features combine to meet the object of the invention by providing a display that facilitates safer use of the apparatus than the prior art.

5.4. It is clear that the extent of the shockwave effective region depends on the shockwave amplitude. Nevertheless, claim 1 must be so construed that this region is first determined for a given amplitude, for example that at which the apparatus is intended to be used for a given patient. The teaching of the application is that this region is then bordered, in the display, by the shockwave effective region pattern, and so long as this pattern is confined to be within the object to be treated, then no harm can come to surrounding biological tissue. This teaching forms the basis for the characterising features of claim 1.

5.5. This teaching is not in the prior art. Neither of documents D1 or D3 discloses determining the shockwave effective region, or defining a shockwave effective region pattern, or displaying a superimposed image of the image of said interior area and the shockwave effective region pattern.

In document D1 there is mention of the focal spot having a luminosity proportional to the corresponding energy concentration, which represents the energy distribution of the shock wave during firing (page 7, lines 2 to 7).

However, at most this means that a fuzzy focal spot is produced, whose intensity fades from the centre towards the edges of the spot, but the extent of the effective part, that capable of influencing tissue, will not be known. Therefore, this apparatus will not overcome the present problem since the extent of the effective region of the shockwave is not known.

Moreover, the display will consist, not of a pattern surrounding the effective region, but of the focal spot itself superimposed on the object to be treated, and, therefore, obscuring it. This could also lead to the shockwaves aimed at the object to be destroyed damaging healthy tissue instead.

The same considerations apply to the apparatus of document D3. This document discloses providing a line on the display to represent a shockwave effective region or "Wirkungsbereich". Apart from being a one-dimensional representation, this display will have the same shortcomings as that of the apparatus of document D1.

5.6. Therefore, an evaluation of the present problem and solution leads to the conclusion that the claimed invention is not an obvious development of the apparatus of document D3.

6. There are further reasons why the present invention is not an obvious development of the prior art apparatus, as follows:

- (a) Document D3 discloses the use of "effect lines" (Wirkungslinie) of the shock wave generators (page 2, lines 8 to 23 and page 4, lines 10 to 16). First and foremost, these are lines, which lines are defined in

claim 1 of this document as an essential feature since their purpose is to indicate the direction of the shockwaves (page 6, lines 24 and 25). The fact that these lines may be limited in extent to a "Wirkungsbereich" is an ancillary feature and is relegated to claim 3. It would not be in keeping with the primary purpose of this line to change it into a two-dimensional feature of the type exemplified by Figure 3 of the application, since it would then no longer indicate the direction along which the shockwaves propagate. Therefore, the development of the one-dimensional line into a two-dimensional feature would make no sense in the context of the disclosure of document D3. For the examining division to say that "it would be obvious to the person skilled in the artthat an indication of a second dimension is missing in order to properly represent the full region" is not correct since no second dimension is required in the context.

- (b) The examining division's assertion that "a contour of the mentioned region is then the most natural and straightforward design measure which the skilled person would readily envision for an improved representation of the shock-wave effective region" is also not supported by the prior art, in which the focal spot, when it is shown by a two-dimensional representation, is always depicted as a filled-in (i.e. opaque) spot or a cross.

Thus document D1 talks of a "tache focale" on the display screen on page 7. This term and the corresponding term "focal spot" in English, both suggest an opaque and fuzzy spot. In document D3 the focus is represented by a line. Otherwise the focal

point is depicted as cross-hairs (Fadenkreuz), see the cross-hairs 24 in the Figure of document D3, and also the opening passages of the present application, for example.

There is no evidence that the focal region has been represented on a display screen in the prior art as a pattern that surrounds a central area so as to enable the underlying image of the biological body to be seen. Thus, the examining division's assertion in this respect is also not valid.

- (c) Moreover, the examining division equates the term "Wirkungsbereich" of document D3 with the shockwave effective region of the application, but this is not justified.

In the application, the effect of the shockwaves in the effective region pertains to the effect on healthy tissue and not the object to be destroyed. This is expressed clearly in claim 1 and explained on page 2, lines 23 to 26 and page 8, lines 21 to 25 of the application as originally filed. Also, the passage on page 3, lines 4 to 14 says that "medical effects caused by the shockwaves or continuous ultrasonic wave may give adverse influences to a normal biological tissue around this marked end position of the biological body, and may cause harmful side effects thereon. There is another drawback that if the size of this effective region is greater than that of the object to be cured, the actual medical influences caused by the shockwaves or continuous ultrasonic wave may be given to the normal biological tissue around this object to be cured, so that the area defined by this normal biological

tissue may be medically damaged." Therefore, the shockwave effective region defined in claim 1 of the application refers to the effect on healthy tissue.

The "Wirkungsbereich" of document D3 refers, on the other hand, to the effect on the object to be destroyed. The expression "Wirkungsbereich" is not explained explicitly, but it is reasonable to assume that it is the effect on the object to be treated that is being referred to since this is consistent with the remainder of the prior art in which what is of interest is the effect of the shockwaves on the object. This is supported to some extent by the passage on page 2, lines 20 to 23 of document D3, which appears to say that even if the calculus is not fully at the focus position it may be determined whether an effective fragmentation thereof can occur, if the length of the line corresponds to the effective region.

Therefore, the Wirkungsbereich of document D3 is not quite the same thing as the shockwave effective region of the application, so that the extension of the one-dimensional Wirkungsbereich of document D3 to the two-dimensional region of the application is not the simple development that the examining division suggests.

The above are further reasons why the person skilled in the art, faced with the problem of the application, would not find a solution in document D3.

7. Therefore, the documents D1 and D3, taken either singly or in combination, do not relate to the problem set out in the application, see point 5.2 above, nor do they suggest any

feature that would solve this problem. Neither do they suggest the particular solution defined in claim 1 of the application. The apparatus of claim 1 involves an inventive step, accordingly.

7.1. The same arguments apply to claim 2.

8. For the above reasons the claims of the main request also meet the requirements of Article 52(1) 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