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D E C I S I O N
of 14 April 1999

Case Number: T 0142/96 - 3.2.2

Application Number: 89112008.1

Publication Number: 0351610

IPC: A61B 19/00

Language of the proceedings: EN

Title of invention:

Ultrasonic apparatus for therapeutical use

Applicant:

Hitachi, Ltd.

Opponent:

-

Headword:

Ultrasonic apparatus/HITACHI LTD.

Relevant legal provisions:

EPC Art. 109(1), 54, 56, 106(1), 107
EPC R. 67

Keyword:

"Admissibility of appeal against a decision on rectification -
yes"
"Refund of the appeal fee - yes"

Decisions cited:

-

Catchword:

-



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Boards of Appeal

Chambres de recours

Case Number: T 0142/96 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 14 April 1999

Appellant: Hitachi, Ltd.
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Tokyo 101 (JP)

Representative: Strehl Schübel-Hopf & Partner
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Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 9 March 1995
refusing European patent application
No. 89 112 008.1 pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: W. D. Weiß
Members: R. K. Shukla
C. Holtz

Summary of Facts and Submissions

- I. European patent application No. 89 112 008.1 relating to an ultrasonic apparatus for therapeutical use was refused in a decision, dated 6 April 1994 (hereinafter "*First decision*"), of the examining division on the ground of lack of novelty having regard to a prior art document D3 - DE-A-3 119 295. Following an appeal by the applicants, the examining division rectified the first decision in a decision pursuant to Article 109(1) EPC, dated 30 September 1994, in view of amendments to claim 1 of the applicants' main request. During the subsequent examination proceedings pursuant to Article 96(2) EPC, a new claim 1 was filed, which was considered by the examining division to lack novelty having regard to the same document D3. The application was accordingly refused in a decision dated 9 March 1995 (hereinafter "*Second decision*").

The applicants lodged an appeal against the second decision and filed with the statement of the grounds of appeal, dated 19 July 1995, three sets of claims forming respectively the basis of a principal request and first and second auxiliary requests. In view of the amendments to claim 1 of the principal request in relation to claim 1 forming the basis of the second decision, the examining division rectified the second decision in a decision dated 15 September 1995.

During the examination proceedings following the rectification, the applicants were informed that claims 1 of the principal and auxiliary requests did not involve an inventive step having regard to document

D3.

II. The present appeal filed on 24 November 1995 is against the decision on rectification, dated 15 September 1995, of the second decision. The appeal fee was paid on 24 November 1995 and the statement of the grounds of appeal was filed on 25 January 1996. The applicants have requested that (i) the decision on rectification dated 15 September 1995 and the second decision of the examining division refusing the application be set aside and a patent be granted on the basis of any of the three requests, i.e. a principal request, a first auxiliary request and a second auxiliary request, filed with the statement of the grounds of appeal, dated 25 January 1996, that (ii) in the event that the Board did not intend to grant a patent, oral proceedings be appointed, and that (iii) the three appeal fees be refunded.

III. The applicants submissions in the statement of the grounds of appeal can be summarised as follows:

Refund of the appeal fees

In the examining proceedings which led to the first refusal of the application in the decision dated 6 April 1994, the applicants had earnestly attempted to overcome the objections raised in the official communications, so that the first decision refusing the application was completely unexpected. Moreover, the objection against the wording of claim 1 in the official communication, dated 19 August 1993, was of such a nature that it would have been more appropriate if the examining division had discussed it over the

telephone before refusing the application. In the examination proceedings following the first rectification, the two-part formulation of claim 1 as suggested by the examining division was adopted, and certain further minor changes were made to the wording of the claim, so that the second refusal of the application was also unexpected. From the communication dated 18 September 1995 of the examining division following the second rectification, it is apparent that claim 1 which was earlier considered to be allowable, was now considered to lack an inventive step over a newly cited document D4. It is thus evident that the present appeal could have been avoided if the examining division either had not changed its opinion formed prior to the second refusal about the patentability of the claims of the second auxiliary request (identical to those which were previously suggested by the examining division) and allowed at least these claims or not rectified its second decision.

Patentability

In the ultrasonic therapy apparatus of the present invention a transducer arrangement first generates an ultrasonic wave which causes cavitation at an intended position within a patient's body where a drug is located and subsequently generates a second ultrasonic wave overlapping the first one to rupture the cavitation, and thereby, to activate the drug. The second wave may differ from the first wave by its focal position or acoustic pressure distribution. Moreover, a high resolution image of the cavitation is obtained by arranging detectors which receive either fractional or higher harmonics of the first ultrasonic wave which

causes the cavitation.

In none of the prior art documents cited in the examination proceedings,

D1: EP-A-0 194 896

D2: Japan Journal of Hyperthermic Oncology, 1987,
vol. 3, No. 2, pages 175 to 182

D3: EP-A-3 119 295

D4: EP-A-0 170 416 and

D6: EP-A-0 248 532,

there is any suggestion that a combination of individual features known from the above prior art would be suitable to meet the specific object of the present invention, namely to provide an ultrasonic therapeutic apparatus which has a high effect on locally activating a drug at a desired location with an extremely low side effect on the normal tissue.

Although document D2 deals with the same object, there is no disclosure of a control means for causing a cavitation and its subsequent rupture, nor is there any teaching to display an image based on fractional or higher harmonics of a first ultrasonic wave. The remaining documents do not provide a hint to the solution of the specific problem which is outside their fields of application, are silent about the control of an ultrasonic transducer as set forth in claim 1, and do not suggest that fractional or higher harmonics are particularly suitable for determining the cavitation.

IV. In a communications dated 26 August 1996 from the Board, the applicants were informed of the Board's preliminary view that the refund of the first and second appeal fees did not appear to be equitable and that the circumstances leading to the third appeal apparently justified the refund of the third appeal fee.

In a communication dated 4 June 1998 accompanying the summons to oral proceedings, the Board informed the applicants that claims 1 of all the requests were apparently not clear, and that claim 1 of the main request did not appear to contain an inventive step.

V. In response, the applicants filed a set of new claims 1 to 6 and new pages of the description, and requested the grant of a patent on the basis of the following application documents:

Claims: 1 to 6 filed with the letter dated 12 July 1998;

Description: pages 1, 3 to 27 filed with the letter dated 17 December 1993;
pages 2 and 2a filed with the letter dated 12 July 1998;

Drawings: sheets 1 and 8 filed with the letter dated 17 December 1993; and
sheets 2 to 7 and 9 to 13 as originally filed.

In view of the amendments to claim 1, oral proceedings were no longer considered necessary, and were

cancelled.

VI. Claim 1 of the above request has the following wording:

"An ultrasonic therapy apparatus comprising transducer means (1-1 ~ 1-N) consisting of a plurality of arranged elements; driving means (2-1 ~ 2-N, 6-1 ~ 6-N, 21) for driving at least part of said transducer means (1-1 ~ 1-N) so as to generate convergent ultrasonic waves, detector means (3-1 ~ 3-N, 5-1 ~ 5-N, 22) arranged to receive fractional or higher harmonic components of a first convergent ultrasonic wave reflected from a cavitation by detecting an acoustic pressure minimum of the acoustic field generated by the first ultrasonic wave, the detector means being adapted to provide a signal to control means (20) when the size of the cavitation is judged to be greater than a predetermined standard, and control means (20) arranged to switch driving means (2-1 ~ 2-N, 6-1 ~ 6-N, 21) in response to said signal from the detector means (3-1 ~ 3-N, 5-1 ~ 5-N, 22), so as to drive the transducer means (1-1 ~ 1-N) to radiate a second convergent ultrasonic wave having an acoustic field with its pressure maximum at the location of the acoustic pressure minimum produced by the first convergent ultrasonic wave, so as to rupture the cavitation."

Claims 2 to 6 are dependent claims.

Reasons for the Decision

1. *Admissibility*

The notice of appeal, and the statement of the grounds of appeal have been filed in due time in accordance with Article 108 EPC. Also, the decision on rectification, dated 15 September 1995, of the second decision is an appealable decision within the meaning of Article 106(1) EPC. The only issue which needs to be considered with regard to the admissibility of the appeal is, therefore, whether the applicants can be regarded as being adversely affected by the decision on rectification pursuant to Article 107 EPC, first sentence.

As mentioned in section I above, in the second decision the application was refused on the ground that the invention as claimed in claim 1 was not novel in relation to a prior art document D3, pursuant to Article 54(1) and (2) EPC. From the communication of the examining division, dated 18 September 1995 following the rectification of the second decision, it would appear that the examining division considered the appeal to be well founded in that the amended claim 1 filed with the grounds of appeal against the second decision met the objection of lack of novelty which was the sole legal basis of the second decision. The subject-matter of claim 1 was however regarded as obvious in relation to document D3 (see Section II, page 2, last paragraph of the above communication). The finding of lack of inventive step was however based on an interpretation of the disclosure in document D3 which was the same as that which had led to the finding of lack of novelty in the second decision and which had been disputed by the applicants (see the statement of

the grounds of appeal, dated 19 July 1995, page 2, last paragraph).

During the examination proceedings, the grounds which form the basis of a decision should not be interpreted to mean only the legal basis of the decision but also the factual reasons supporting the legal basis. In the present case, although the legal basis of the decision, i.e. the requirement of Article 54 EPC, was considered to have been met, substantial differences between the examining division and the applicants regarding the essential factual reasons were not resolved. The decision on rectification thereby deprived the applicants from an examination by the appeal board of the contentious factual issues which formed the basis of the second decision. In the Board's view, therefore, the applicants were adversely affected by the decision on rectification (cf. decision T 691/91 of 29 July 1992).

For the foregoing reasons, the appeal is admissible.

2. *Amendments*

Amended claim 1 is based on claims 7 and 9 and the description on page 3, line 25 and page 4, lines 20 to 25, of the application as originally filed. The subject-matter of claim 2 is based on the disclosure, for example, on page 7, lines 7 to 15, of the application as originally filed. Claims 3 to 5 are based on claims 8, 10 and 11, respectively, and claim 6 is based on the disclosure on page 14, line 34 to page 15, line 2, of the application as originally filed.

The description has been amended to acknowledge the prior art documents and for consistency with the amended claim 1, and includes minor editorial amendments.

The new drawings, i.e Figure 1A and Figure 9 have been amended to correct spelling mistakes in the legends.

The application as amended therefore complies with the requirement of Article 123(2) EPC.

3. *Novelty*

The present invention as disclosed and claimed relates to an ultrasonic therapy apparatus based on the use of a cavitation effect and the rupture of the cavitation to activate a drug located within the body of a patient. To this end, as set out in claim 1, the apparatus comprises:

- (i) detector means (1-1 ~ 1-N; 3 - 1 ~ 3-N ; 5-1~5N; 25) which are arranged to detect fractional or higher harmonic components of a first convergent ultrasonic wave, reflected from a cavitation, and to thereby locate the cavitation by detecting acoustic pressure minimum of the acoustic field generated by first ultrasonic wave;
- (ii) the detector means being adapted to provide a signal to control means (20) when the size of the cavitation is judged to be greater than a predetermined standard; and

(iii) control means (20) which is arranged to switch driving means (2-1~2-N; 6-1~6-N, 21), in response to said signal from the detector means, so as to drive the transducers (1-1 ~ 1-N) to radiate a second convergent ultrasonic wave having an acoustic field with its acoustic pressure maximum at the location of the acoustic pressure minimum produced by the first convergent ultrasonic wave, so as to rupture the cavitation.

With regard to the wording of claim 1, the Board observes that the driving means, detector means and the control means are limited by their respective functions as set out in the claim, and these means are not to be regarded as only being suitable for these functions.

Document D1 concerns an ultrasound therapy system comprising an array of ultrasound transducers, a tomographing processor for driving the array by a first drive signal to transmit and receive ultrasound echo waves reflected from the internal tissues of a patient, to thereby form a tomogram of the internal tissues, a treating controller for driving the array by a second drive signal to transmit ultrasonic wave for treatment purpose (see page 3, lines 12 to 23; page 7, lines 1 to 12). The system is thus selectively operable in an image forming mode or a treatment mode. There is however no disclosure that in the image forming mode, the transducers are adapted to detect an acoustic pressure minimum and to provide a signal to a control means in response to such a detection, as set out in features (i) and (ii) above. Moreover, the apparatus is not provided with a control means which is adapted to

switch a driving means in response to the signal from the detector, to drive the transducers to produce a second ultrasonic wave having an acoustic field with its acoustic pressure maximum at the location of the acoustic pressure minimum produced by the first convergent ultrasonic wave (see feature (iii) above).

Document D2 reports the results of a study of the treatment of tumours using ultrasound to activate antitumour drugs in the tumour. The document, however, does not describe any apparatus, and, in particular, the detection of cavitation and the control means for driving the transducers so as to rupture the cavitation in response to such a detection.

Document D3 describes an ultrasound therapy apparatus for fragmenting concretions in a body, comprising (see page 6, line 10 to page 7, line 24; Figure 2):

- an array of transducer elements (15) driven by a signal generator (19);
- a control circuit (17) for electrically changing the focal length of the array, so that the array is capable of irradiating ultrasonic waves having overlapping focal zones;
- detector means (15, 21) for detecting the echo signals from an object (6) to be treated; and

- display means (22) for forming an image of the irradiated body area from the output signals of said detector means.

The detector means, however, do not provide a signal to the control circuit in response to detection of an acoustic field minimum as set forth in feature (i) above, and the control circuit also does not respond to such a signal as set out in feature (iii) above.

Document D4 concerns an ultrasound hyperthermia apparatus having an ultrasound probe (3) providing a tomographic image and a heating applicator (4) for radiating a focussed ultrasound beam for heating a tumour (21). The hot spot, i.e. the focus of the ultrasound beam from the applicator, may be determined by the tomographic image probe (3) detecting harmonic components of the heating ultrasound beam reflected from the irradiated portion of the body (see the abstract, page 3, lines 9 to 37, page 5, line 33 to page 6, line 6, Figures 1 and 3 to 6). However, there is no control signal in response to such a detection of hot spot for driving the applicator to produce a second ultrasound beam as defined in feature (iii) above.

Document D6 describes an ultrasonic hyperthermia apparatus comprising an array of wide bandwidth ultrasonic treatment transducers (20-49) and imaging transducers (53-56) driven by an electronic read out system (96). The imaging ultrasonic transducers are driven by electrical energy supplied by the electronic read out system and respond to the energy reflected back to them to derive a two-dimensional image of the region to be treated (see, e.g. column 5, lines 33 to

37, column 8, lines 11 to 17 and lines 26 to 33, column 13, lines 20 to 30, Figures 1 and 2). The imaging transducers thus do not detect fractional or higher harmonic components of an ultrasonic wave beam generated by the treatment transducers (20-49), and thereby detect acoustic pressure minimum of the acoustic field generated by this ultrasonic wave (see feature (i) above). The B-scan display on a cathode-ray tube (95) described in column 13, lines 5 to 13 also does not detect the acoustic field minimum as in feature (i) above, so that there is no signal from the treating transducers to a control means as set out in feature (ii) and there is no control means for driving the treating transducers as defined in feature (iii) above.

The remaining documents cited in the European search report are no more relevant than the ones discussed above. The subject-matter of claim 1 is accordingly new within the meaning of Article 54(1) EPC.

4. *Inventive step*

From the above discussion of the cited prior art, it is evident that the documents either taken alone or in combination do not disclose or suggest a combination of the above features (i), (ii) and (iii). Only document D2 is relevant in so far it discloses the use of an ultrasound wave to activate the drug located in the tumour. As already mentioned above, this document, however, does not describe any apparatus having the features (i), (ii) and (iii) above.

For the foregoing reasons, in the Board's judgment,

claim 1 also involves inventive step within the meaning of Article 56 EPC.

5. *Refund of the Appeal fees*

5.1 With regard to the request for the refund of the first appeal fee, from the facts of the present case, it is evident that the refusal of the application in the first decision was in accordance with the requirements of the convention. In particular, the applicants' right to be heard according to Article 113(1) were not contravened by the issue of the decision, so that, in the Board's judgment, there was no procedural violation justifying the refund of the appeal fee (see also below, point 5.4).

5.2 According to Rule 67 EPC, the reimbursement of an appeal fee is to be ordered if the following conditions are fulfilled:

1. where the board of appeal deems an appeal to be allowable; and
2. if such reimbursement is equitable by reason of a substantial procedural violation.

5.3 The possibility for reimbursing an appeal fee under Rule 67 EPC serves the purpose of compensating an appellant who had to file an appeal unnecessarily due to a substantial procedural violation committed by the first instance.

In the present case it is clear that the "decision on rectification" of the second decision represents a

substantial procedural violation. This board concurs fully with the board in decision T 691/91 in its finding that Article 109 EPC provides two legally viable alternatives: to maintain or to annul the decision under appeal, and that, parallel to the circumstances of that case, the present decision on rectification presents a third alternative, that of in fact maintaining a previous decision to refuse the application, albeit this time, after the appellant amended the claims, on the basis of lack of inventive step rather than lack of novelty. As was said in the previous case, Article 109 EPC does not provide a legal basis for this latter alternative.

The board in decision T 939/95 (OJ EPO 1998, 481) discussed the merits of a practice that had evolved over the years in the first instance, namely to annul the previous decision without immediately replacing it with a decision to grant the patent. Instead the examination would be re-opened. The board held that this practice was, from the point of view of the public interest, questionable at best, although understandable, in so far as time could be saved if remaining issues could be dealt with by the first instance instead of having to be resolved by a board of appeal. On the one hand, the board referred to the Guidelines for examination in the European Patent Office, E-XI, 7 and 9, according to which a decision to rectify should only be taken if the appeal had cleared any outstanding issue to such an extent that the first instance immediately could establish that the amendments made on appeal met the objections raised and that the appeal therefore was well founded or at least did not necessitate any further contacts with the

applicant through communications or otherwise. On the other hand, the board also observed that from the short time allotted under Article 109 EPC for rectification the opposite conclusion could be drawn, namely that rectification without replacing the annulment by a decision to grant the patent was acceptable.

5.4 The present case is a very good example of how a procedure may be unduly prolonged through numerous communications and several decisions to rectify without coming to a conclusion as to whether the invention is patentable or not. As long as the appellant did not question the measures taken by the examining division and these measures were appropriate in view of the situation at hand, the board would not however conclude that the examining division committed any substantial procedural violation. This is the case regarding the first decision to refuse the application and the decision to rectify that decision on appeal by the appellant, see above point 5.1.

5.5 As to the present appeal against the decision to rectify the second decision, the situation is different. Only the novelty question was at issue in the first two decisions, and on rectification of the second decision, this issue was resolved in favour of the appellant despite the fact that substantial differences between the appellant and the examining division regarding the essential factual reasons leading to the refusal of the application were not resolved (see point 1.0 above). The decision on rectification was therefore contrary to the principle of procedural economy underlying Article 109 EPC. The board concludes that this constituted a substantial

procedural violation which gave rise to the present, unnecessary appeal. The board also considers that a reimbursement of the appeal fee for the present appeal is equitable under the circumstances.

- 5.6 The question is then if the second condition of Rule 67 EPC - "where the Board of Appeal deems the appeal allowable" - has been met when an appellant has amended the claims during the appeal review in response to objections raised by the board or if reimbursement is to be ordered only where the requests on appeal against the second decision in themselves, *prima facie*, were allowable. Since - as is said above - the purpose of the refund is to compensate an appellant for having to file an unnecessary appeal - the board would find Rule 67 EPC satisfied whenever the appeal is allowable, regardless of at which stage of the appeal procedure the appellant made a favourable decision possible through further amendments. This is so because there is no possibility for the appellant to establish beforehand what the opinion of the board may be on the requests filed with the notice of appeal or the grounds of appeal. Insofar as an appellant has overcome objections raised by the board, it should therefore be entitled to a reimbursement under Rule 67 EPC, provided that the other conditions of that Rule have been met.

Order

For these reasons it is decided that:

1. The case is remitted to the department of the first instance with the order to grant a patent with the text and drawings as specified below:

Claims: 1 to 6 filed with the letter dated
12 July 1998;

Description: pages 1, 3 to 27 filed with the letter
dated 17 December 1993;
pages 2 and 2a filed with the letter
dated 12 July 1998;

Drawings: sheets 1 and 8 filed with the letter
dated 17 December 1993; and
sheets 2 to 7 and 9 to 13 as originally
filed.

2. The appeal fee for the present appeal against the decision of 15 September 1999 shall be reimbursed.

The Registrar:

The Chairman:

S. Fabiani

W. D. Weiß

In application of Rule 89 EPC, the decision given on 14 April 1999 is hereby corrected as follows:

Order, point two: Replace "1999" with "1995".

The Registrar:

The Chairman:

S. Fabiani

W. D. Weiß