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Datasheet for the decision of 15 May 2012

Case Number: T 1868/08 - 3.4.01

Application Number: 01998377.4

Publication Number: 1349612

IPC: A61N 7/02

Language of the proceedings: EN

Title of invention:
Thermal Treatment System

Patentee:
Insightec-Txsonics Ltd.

Opponent:
-

Headword:
-

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

Relevant legal provisions (EPC 1973):
EPC Art. 84

Keyword:
"Inventive step - (yes) after amendment"

Decisions cited:
-

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 1868/08 - 3.4.01

D E C I S I O N
of the Technical Board of Appeal 3.4.01
of 15 May 2012

Appellant: (Applicant)
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Decision under appeal:
Decision of the Examining Division of the European Patent Office posted 20 March 2008 refusing European patent application No. 01998377.4 pursuant to Article 97(2) EPC.

Composition of the Board:

Chairman: G. Assi
Members: F. Neumann
M. J. Vogel

Summary of Facts and Submissions

I. The appeal, filed on 19 May 2008, lies from the decision of the examining division, dispatched on 20 March 2008, to refuse European patent application number 01 998 377.4. The appeal fee was paid on 19 May 2008. The statement setting out the grounds of appeal was filed on 29 July 2008.

II. The following documents, cited in the international search report, will be referred to in the present decision:

D1: US-A-6 128 522,
D4: US-A-5 485 839,
D5: US-A-5 722 411.

III. The examining division refused the application for lack of clarity and added subject-matter of the main request, lack of novelty of the first and second auxiliary requests and lack of clarity of the third auxiliary request.

With the statement of grounds of appeal, the appellant filed two sets of claims forming a new main request and first auxiliary request respectively. An attempt was made to overcome the objections of the decision in the wording of the new claims and arguments were submitted in support of novelty of the independent claim of the main request. In particular, it was submitted that in D1 the temperature of a target mass is monitored during the delivery of a series of ultrasound sonications. Application of the ultrasound energy is terminated when a treatment site reaches the desired ablation

temperature. In contrast thereto, the present invention monitors the temperature in order to establish the applied thermal dose. The treatment plan may be adjusted after each sonication to take account of any discrepancy between the predicted (planned) thermal dose and the thermal dose actually received by the tissue. In this way predictions are continually aligned with reality and the treatment plan evolves as treatment progresses.

In a communication of the Board dated 21 February 2012, a number of clarity objections were raised. In particular, it was held that the use of the term "thermal dose" was not clear in claim 1. Also, it was held that the function and interaction of various components of the claimed system was not clear.

In response to this communication, by letter of 23 March 2012, the appellant filed three sets of claims forming the basis of a main request and first and second auxiliary requests. Further informal discussions with the appellant then resulted in a draft of claims 1-10 forming an amended main request filed with a letter of 19 April 2012.

IV. The appellant has requested that the decision under appeal be set aside and that a patent be granted on the basis of claims 1-10 filed as a main request with the letter of 19 April 2012. In addition, the two sets of claims forming the first and second auxiliary requests filed with the letter of 23 March 2012 remain on file.

V. Claim 1 of the main request reads:

"*A focused ultrasound system (500) comprising:*

a transducer (102) for delivering successive ultrasound sonications (112) at various treatment sites within a target mass (104) in a patient (116) to ablate the target mass (104);

a controller (106) for controlling the electrical properties and mechanical positioning of the transducer (102) in order to control the properties and treatment sites of the ultrasound sonications (112);

an MR imager (502) for providing preliminary MR images of the target mass (104) before a treatment is carried out, and, during the treatment, for providing temperature sensitive MR image sequences of the target mass (104), illustrating the actual thermal dose distribution (606) in the target mass (104) resulting from each successive ultrasound sonication delivered to the target mass (104);

a planner (108) configured to automatically construct a treatment plan using the preliminary MR images, for applying a series of predetermined ultrasound sonications to predefined treatment sites of the target mass (10), the planned sonications causing ablation of a predicted amount of tissue around each treatment site, the plan being constructed to ensure ablation of the entire target mass (104);

the planner (108) being further configured

to construct a predicted thermal dose distribution illustrating the predicted thermal dose threshold contours around each treatment site in the treatment plan, the contours representing the region in which the predicted amount of tissue is to be ablated,

to compare the MR images of the actual thermal dose distribution (606) resulting from the delivered ultrasound sonications to the predicted thermal dose distribution (608) to determine how closely the actual treatment is tracking the treatment plan, and,

if necessary, to adjust the treatment plan after each delivered ultrasound sonication so that no untreated regions remain."

Claims 2 to 10 of the main request are dependent claims.

VI. Reference is made to the transitional provisions for the amended and new provisions of the EPC, from which it may be derived which Articles of the EPC 1973 are still applicable to the present application and which Articles of the EPC 2000 shall apply.

Reasons for the Decision

1. The appeal is admissible.

2. *Main request*

2.1 Article 123(2) EPC

A word-for-word correspondence between the new claims and the original disclosure does not exist. Nevertheless, the Board considers that the subject-matter of the amended claims may be derived in a direct and unambiguous manner from the teaching of the original application. The requirements of Article 123(2) EPC are therefore fulfilled.

Claim 1 is based on original claims 15, 16 and 17 with additional explanatory passages to aid the clarity of the claim. Basis for the controlling of electrical properties and mechanical positioning of the transducer may be found on page 11, line 21 to page 12, line 14. Basis for the reference to the temperature sensitive MR image sequences may be found on page 14, lines 1-3; page 17, lines 20-21; page 20, lines 19-24. That the planned sonications cause ablation of a predicted amount of tissue is derivable from Figures 7A and 7b in combination with page 17, lines 13 to 19. Page 12, lines 15 to 19 makes clear that the plan is constructed to ensure ablation of the entire target mass. The reference to the predicted temperature threshold contours may be derived from page 6, lines 3-5. That the contours correspond to the region in which the predicted amount of tissue is to be ablated may be derived from Figures 7A and 7B in combination with

page 17, lines 13 to 19. The comparison of the predicted and actual images to determine how closely the actual treatment is tracking the treatment plan is derived from page 20, line 24 to page 21, line 2. That the plan is only adjusted *if necessary* and until no untreated regions remain is derived from page 21, lines 2 to 13.

2.2 Article 84 EPC 1973

During the appeal proceedings, the clarity of the term "thermal dose" was discussed. The term was used in the previous versions of the claims to describe two things, namely the amount of energy provided by the individual ultrasound sonications and the accumulated amount of temperature exposure of the target mass.

Whilst some doubts remain as to whether a standardised manner of quantifying thermal dose was agreed upon among experts at the priority date of the application, the Board is convinced that the concept of thermal dose was indeed understood at that date. The Board considers that the skilled person would have interpreted this term as providing a measure which reflects the accumulated amount of temperature exposure throughout the treatment period, for example by reference to an exposure time at some reference temperature.

Although the application of ultrasound energy does indeed contribute to the accumulated temperature exposure of the tissue, the reference in former claim 1 of the main request filed by the letter of 23 March 2012 to a "thermal dose of ultrasound energy" was held to be confusing in the light of the later references in

the claim to the "thermal dose distribution" and "thermal dose contours".

The ultrasound energy applied to the target mass is now simply referred to in claim 1 of the current main request as an "ultrasound sonication" and the use of the term "thermal dose" is now restricted to the above meaning which the Board considers to be the conventional understanding of this term in the context of hyperthermia therapy.

2.3 Articles 52(1), 54, 56 EPC

2.3.1 In general terms, the invention concerns a focused ultrasound system for clinical hyperthermia and is essentially a thermal treatment system which is used to ablate a tissue mass (typically a tumour) in a patient.

A planner is configured to draw up a treatment plan in advance of the treatment which defines a number of treatment sites within the target mass to be treated and fixes the amount of ultrasound energy to be delivered to each treatment site. The energy applied by each sonication heats the tissue surrounding the treatment site with the result that the thermal dose around that particular site increases. Those portions of the tissue which have accumulated a certain threshold thermal dose will become ablated. The aim of the treatment plan is to ensure that the threshold thermal dose is acquired throughout the entire target mass so as to ensure complete ablation thereof.

In practice, the actual response of the tissue to the applied energy depends on a number of factors including, for example, the thermal conductivity of the tissue and blood flow. Therefore neither the spatial extent of the heating around the treatment site nor the resulting accumulated thermal dose can be accurately predicted. The invention recognises that the treatment plan may not have the expected thermal effect, the planner being thus configured to adjust the treatment plan to compensate for the discrepancy between the predicted behaviour and what has actually happened so as to ensure that the accumulated thermal dose at each point in the tissue is sufficient to ablate the entire mass.

2.3.2 D1 represents the closest prior art. This document discloses a focused ultrasound system for thermally ablating unwanted tissue.

Before treatment commences in D1, an MR imager provides a preliminary MR image of the region of the patient to be treated (column 16, lines 1-21). On the basis of this image, a target mass is identified (column 16, lines 22-24) and a number of individual treatment sites within the target mass are selected (this is clear from column 18, 21-24 and 59-64). On the basis of the temperature response at a number of test locations around the treatment region, a treatment plan is drawn up by a control computer 29 (column 17, line 54 to column 18, line 17; column 18, lines 29-34). This plan sets the amount of focussed ultrasound energy which is to be applied at each specific treatment site in order to heat the tissue at these treatment sites to a temperature sufficient to ablate the tissue (column 18,

lines 17-34). As the thermal treatment is being performed, the temperature of the tissue currently being sonicated is monitored by capturing a continuous MRI temperature map (column 19, lines 1-12; column 24, lines 25-37). On the basis of this temperature information, the heating process can be terminated when the site reaches the temperature necessary for ablation or prolonged if the temperature required for ablation has not yet been achieved (column 24, lines 30-37). Thus, the treatment plan is adjusted to take account of a rise in temperature which is faster or slower than expected at any one treatment sites.

2.3.3 Although the system set out in claim 1 of the main request is similar to the system of D1, there is a significant difference concerning the information which is used to adjust the treatment plan.

Specifically, in claim 1, the planner is configured not only to construct a treatment plan, but is also configured to construct a predicted thermal dose distribution which illustrates the contours outlining the region around each treatment site in which the predicted thermal dose exceeds the threshold for causing ablation. Thus the contours depict the predicted extent of thermal ablation around each of the treatment sites.

During the treatment in claim 1, a planned predefined amount of energy is delivered to each specific treatment site. This predefined amount of energy contributes to the thermal dose received in the tissue surrounding each treatment site. An actual thermal dose distribution is derived from temperature sensitive MR

image sequences taken during the treatment thus enabling the continuous monitoring of the accumulated temperature exposure throughout the entire tissue mass. Since the level of thermal dose at any one point is indicative of whether or not ablation has occurred at that point, the actual thermal dose distribution is representative of the spatial extent of the ablation around each treatment site.

In the current application, the actual thermal dose distribution is compared to the contours of the predicted thermal dose distribution to establish whether the actual extent of the ablation corresponds to what was predicted. If not, then the plan is adjusted accordingly.

This is in contrast to the situation in D1 in which the MR temperature images only provide a snapshot of the temperatures currently prevailing in the tissue at that time. The heating process is controlled on a site-by-site basis, the tissue being heated until the threshold temperature required for ablation has been reached at the treatment site. The imager of D1 gives no information regarding the total thermal dose already accumulated at various other locations within the target mass and therefore cannot provide any indication as to whether these other locations have received a sufficient thermal dose during the treatment period to become ablated.

2.3.4 None of the remaining prior art citations on file suggest the construction of a predicted thermal dose distribution illustrating the contours corresponding to the predicted extent of ablation, the comparison of

these contours with the actual thermal dose distribution and then the adjustment of the treatment plan on the basis of this comparison rather than on the basis of whether the temperature at the current treatment site is responding as predicted. Indeed, the monitoring of thermal dose is not envisioned in the available prior art. The only monitoring which is suggested in D4 and D5 to ensure that the treatment is progressing as desired is the performance of a structural inspection of the treated region by means of MRI or CT scans.

The subject matter of claim 1 therefore does not derive in an obvious manner from the teaching of the cited prior art.

2.4 The main request is allowable.

3. *First and second auxiliary requests*

Since the main request of the appellant can be acceded to, it is not necessary to consider the first and second auxiliary requests.

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 the first instance with the order to grant a patent with claims 1 to 10 of the main request, filed by letter of 19 April 2012, and a description to be adapted thereto.

The Registrar: The Chairman:

R. Schumacher G. Assi