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DECISION
of 10 February 2004

Case Number: T 0641/01 - 3.4.1

Application Number: 91907829.5

Publication Number: 0579599

IPC: A61N 5/02

Language of the proceedings: EN

Title of invention:

Catheters for treating prostate disease

Applicant:

MMTC, Inc.

Opponent:

-

Headword:

Catheters for treating prostate disease/MMTC INC.

Relevant legal provisions:

EPC Art. 84, 56, 123(2), 54(1)-(4)

Keyword:

"Admissibility of amendments (yes)"

"Clarity (yes, after amendment)"

"Novelty and inventive step (yes, after amendment)"

Decisions cited:

-

Catchword:

-



Case Number: T 0641/01 - 3.4.1

D E C I S I O N
of the Technical Board of Appeal 3.4.1
of 10 February 2004

Appellant: MMTC, INC.
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Representative: von Bezold, Dieter, Dr.
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Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 7 December 2000
refusing European application No. 91907829.5
pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: G. Davies
Members: H. K. Wolfrum
M. G. L. Rognoni

Summary of Facts and Submissions

I. European patent application 91 907 829.5 (publication No. 0 579 599) corresponding to published international application WO-A-92/18199 was refused by a decision of the examining division dispatched on 7 December 2000, on the ground of lack of clarity (Article 84 EPC) of the independent claims of a main request and an auxiliary request then on file.

Furthermore, under a heading "additional remarks", the examining division expressed its view that the subject-matter of claims 1 of these requests lacked novelty within the meaning of Articles 52(1) and 54(3) and (4) EPC with respect to an earlier European application according to document:

D8: WO-A-91/11975,

and that the subject-matter of independent claim 6 of the main request directed to a rectal catheter did not involve an inventive step within the meaning of Articles 52(1) and 56 EPC with respect to documents:

D1: US-A-4 823 812, and

D6: US-A-4 662 383.

II. The applicant lodged an appeal against the decision on 5 January 2001 and paid the prescribed fee. On 6 April 2001 a statement of grounds of appeal was filed with an amended set of claims 1 to 17, replacing the former requests.

III. In a communication dated 10 November 2003 and annexed to a summons to oral proceedings the Board referred to the above state of the art as well as to a further earlier European application cited in examination according to document:

D9: WO-A-92/04934.

IV. In response the appellant filed, by letter of 12 January 2004, four sets of claims according to a main request and three auxiliary requests.

V. Oral proceedings were held on 10 February 2004.

As a result of the discussion, the appellant requested that the contested decision be set aside and a patent be granted with the following documents which are an amended version of the previous second auxiliary request:

Claims: claims 1 to 11 filed in the oral proceedings
Description: pages 1, 2, 2a, 3 to 10 filed in the oral proceedings
Drawings: sheets 1/4 to 4/4 as originally filed.

VI. Independent claims 1 and 6 of the appellant's request read as follows:

"1. Rectal catheter adapted to be inserted into the rectum of a male patient, wherein said rectal catheter comprises:

- microwave antenna means (306) for irradiating said patient's prostate (310) with a given distribution

of microwave field intensity, wherein the maximum microwave power to be employed is limited to an amount at which the temperature of the patient's heated tissue most proximate to said microwave antenna means (306) does not exceed a given safe maximum temperature, said microwave antenna means (306) comprising distribution means for providing the distribution of microwave field intensity that preferentially heats said patient's tissue in a direction towards said patient's prostate (310) more than in a direction away from said patient's prostate (310),

- an inflatable balloon (302) inside of which said microwave antenna means (306) is situated, said inflatable balloon (302) being situated at a distance from a tip of the catheter, said distance defining a position of the inflatable balloon (302) which is in cooperative relationship with the prostate to be treated when the catheter is fully inserted, and

- inflating means for inflating said inflatable balloon (302), wherein

- said rectal catheter is adapted to be inserted into said rectum while in a deflated state and positioned therein at a location at which both said inflatable balloon (302) and said microwave antenna means (306) are in cooperative relationship with said patient's prostate,

- said inflatable balloon (302) is inflatable in size from a first cross-section value not larger than the cross-section of said rectum when said inflatable balloon (302) is deflated to a second cross-section value substantially larger than the cross-section of said rectum when said inflatable balloon (302) is inflated,

- wherein, when said inflatable balloon (302) is inflated, both prostate tissue (310) and non-prostate tissue (308) situated between said inflatable balloon (302) and said prostate tissue (310) are squeezed and compressed so as thereby to increase the minimum distance between heated tissue of said patient and said microwave antenna means (306), so that the maximum microwave power may be increased without exceeding said given maximum safe temperature and the temperature differential between the heated prostate tissue (310) more proximate to said microwave antenna means (306) and the heated prostate tissue (310) more distal to said microwave antenna means (306) is reduced, and

- wherein said inflatable balloon (302) when fully inserted and inflated substantially conforms to a bulge in the patient's rectum caused by an enlarged prostate.

"6. Catheter arrangement for treating prostate disease, with a rectal catheter according to one of the claims 1 to 5, and a urethra catheter adapted to be inserted into the urethra of the patient, wherein said urethra catheter comprises:

- microwave antenna means (116, 200) being located substantially on a central axis of said urethra catheter for irradiating said patient's prostate (202) with a substantially uniform angular distribution of microwave field intensity, wherein the maximum microwave power to be employed is limited to an amount at which the temperature of the patient's heated tissue most proximate to said microwave antenna means (116, 200) does not exceed a given safe maximum temperature,

- an inflatable balloon (122, 206) being situated at a distance from a tip (106) of said urethra catheter, said distance defining a position of the

inflatable balloon (122, 206), inside of which said microwave antenna means (116, 200) is situated, and

- inflating means for inflating said inflatable balloon (122, 206), wherein

- said urethra catheter is adapted to be inserted into said urethra, while in a deflated state, and positioned therein at a location at which both said inflatable balloon (122, 206) and said microwave antenna means (116, 200) are in cooperative relationship with said patient's prostate,

- said inflatable balloon (122, 206) when inserted into the urethra is inflatable in size from a first cross-section value not larger than the cross-section of said urethra to a second cross-section value substantially larger than the cross-section of said urethra when said inflatable balloon (122, 206) is inflated,

- wherein, when said inflatable balloon (122, 206) is inflated, both prostate tissue (202) and non-prostate tissue (204) situated between said inflatable balloon (122, 206) and said prostate tissue (202) are squeezed and compressed so as thereby to increase the minimum distance between heated tissue of said patient and said microwave antenna means (116, 200) and to reduce the difference between outer and inner radii (R_{3b} , R_{2b}) of the prostate tissue with respect to the microwave antenna means (116, 200), so that the maximum microwave power may be increased without exceeding said given maximum safe temperature and the temperature differential between the heated prostate tissue (202) more proximate to said microwave antenna means (116, 200) and the heated prostate tissue (202) more distal to said microwave antenna means (116, 200) is reduced."

VII. The appellant's submissions in support of its request may be summarized as follows:

The invention aimed at devising a rectal catheter as well as an arrangement of a rectal catheter and a urethra catheter for an improved hyperthermia treatment of an enlarged prostate. By providing an inflatable balloon which surrounded the microwave antenna means it became possible to squeeze and compress the prostate tissue so that the distance between the antenna and the heated tissue was increased. Such an increase in distance entailed two effects, both of which were based on the fact that the microwave power and thus the thermal energy absorbed in the tissue decreased with an increasing radial distance. Firstly, non-prostate tissue was pushed away from the vicinity of the antenna and thus was heated to a lesser extent. Secondly, the extension of prostate tissue in radial direction was reduced so that the gradient in temperature between tissue more proximate to the antenna and tissue distal from the antenna was reduced. The result of both effects was a more homogeneous and effective heating of the prostate as a whole.

As regards the prior art knowledge, none of the cited documents hinted at the idea to support microwave hyperthermia treatment of the prostate by a catheter having means of applying squeezing pressure to the prostate tissue.

In fact, document D1, relied on by the examining division, showed a conventional rectal catheter for microwave hyperthermia treatment which did not possess any means that would exert squeezing pressure on the

heated tissue. Although the known catheter comprised an inflatable balloon, this balloon served for a different purpose (*ie* to fix the position of the catheter when inserted into the rectum) and did not surround the microwave antenna.

The other document, *ie* D6, cited by the examining division showed an endotract catheter for microwave hyperthermia treatment which comprised an inflatable balloon surrounding the microwave antenna, but the inflated balloon also served a different purpose in that it should come in close contact with the inner wall of the respective organ to be treated and thereby remove any gases or fluids between the antenna and the surface of the organ. Consequently, the balloon was formed of a highly flexible material which had to be as thin as possible so as to absorb as little microwave energy as possible. Thus, apart from the fact that the catheter was not specifically adapted to form a rectal catheter, its balloon was not suitable for exerting substantial squeezing pressure on the surrounding tissue.

Starting from either D1 or D6, the problem addressed by the present invention was to be seen in providing an improved rectal catheter for hyperthermia treatment of the prostate which reduced the risk of overheating non-prostate tissue and rendered the heating of the prostate more homogeneous.

Finally, documents D8 and D9 referred to by the examining division constituted earlier European applications which belonged to the state of the art within the meaning of Articles 54(3) and (4) EPC only.

Since they concerned urethra catheters they did not take away the novelty of the subject-matter of the claims in suit.

Moreover, the claim definitions were clear and disclosed in the originally-filed application documents so that the requirements of Articles 84 and 123(2) EPC were also met.

Reasons for the Decision

1. The appeal complies with the requirements of Articles 106 to 108 and Rule 64 EPC and is, therefore, admissible.
2. *Amendments (Article 123(2) EPC)*

Independent claim 1 is based on originally-filed claims 1, 5 and 9. The wording of these claims is amended by the additional definition of inflating means which are disclosed by Figures 1b and 1c and the corresponding description on page 5, lines 13-17, and page 7, line 33 to page 8, line 1, of the published application, as well as by an explicit definition of the relation of cross-sectional values of the inflatable balloon in the deflated and inflated state, as is supported by the description of Figures 2a and 2b. Although the added features and properties are mentioned, strictly speaking, in the context of the description of a urethra catheter, it is clear from the statement on page 8, lines 19 to 2, of the application: "*In addition, the rectal catheter shown in Figure 3 also possesses the advantages of the urethral catheter,*

discussed above." that they are disclosed for the rectal catheter as well.

The catheter arrangement according to claim 6 is disclosed by original claim 15 and the description on page 10, lines 5 to 7, of the application with the features of the urethra catheter being disclosed by original claim 1 and the description of Figures 1, 1b, 1c, 2a and 2b.

The Board is thus satisfied that the claims on file comply with the requirement of Article 123(2) EPC.

3. *Clarity (Article 84 EPC)*

- 3.1 In its contested decision (cf item 1.1), the examining division held that in particular the features "said inflatable balloon is adapted to be inflated to a given tissue squeezing pressure ... from a first cross-section value ... to a second cross-section value substantially larger than the cross-section of said urethra ... said tissue squeezing pressure being sufficient to squeeze and compress (prostate) tissue of said patient ... so as to increase the minimum distance between heated tissue of said patient and said microwave antenna means and to reduce the difference between outer and inner radii of the prostate tissue with respect to the microwave antenna means" (emphasis added), included in claims 1 of the requests then on file, defined properties of the inflatable balloon by results to be achieved.

The division argued that these definitions were unclear since they did not meet established criteria for the

allowability of functional definitions. According to the examining division, physical properties of diseased prostate tissue varied to a great extent among individual patients. Hence, the claimed result, namely the application of a sufficient tissue squeezing pressure by the inflated balloon, could not be directly and positively verified and was thus considered unclear, the more so as a verification device was neither specified in the description nor known in the art. In any case, a vast number of experiments would have to be carried out in order to determine the proper tissue squeezing pressure, which, apart from ethical problems that might arise with patients, constituted undue experimentation.

- 3.2 The Board notes that the present wording of the claims does no longer require that the balloon should be inflated to a "given tissue squeezing pressure". All that is required is that the balloon is inflatable from a first cross-section value small enough to fit into a patient's rectum or urethra to a second cross-section larger than that of the rectum or urethra so that, in consequence, the inflated balloon will exert a squeezing pressure on the tissue surrounding the catheter and thereby increase the distance between the tissue and the microwave antenna.

As regards the aspect of control over the degree of inflation, the application documents hint on page 8, first paragraph, at the possibility of monitoring not only the proper positioning of the catheter but also the amount of inflation by means of fluoroscopy for a balloon filled with a radio-opaque liquid.

The Board has no doubt that the skilled person, who, in the present case, possesses the qualification of a mechanical engineer developing catheters for medical treatment, under instruction by a physician, would understand the meaning and implications of the claim definitions and, moreover, would have the knowledge as well as the technical means necessary to design a rectal or urethra catheter with an inflatable balloon having the properties specified in the claims in suit.

4. *Novelty and inventive step (Articles 52(1), 54 and 56 EPC)*

4.1 Both of the earlier European applications according to documents D8 and D9, which are comprised in the state of the art within the meaning of Articles 54(3) and (4) EPC, concern urethra catheters. Such catheters differ from a rectal catheter *inter alia* in their outer diameter so that the content of these applications is not detrimental to the novelty of the subject-matter of independent claims 1 and 6 on file.

4.2 As regards the available prior art published before the international filing date of the present application, an example of a conventional rectal catheter is given by document D1 (see in particular Figure 1 with the corresponding description). The known catheter comprises an inflatable balloon and corresponding inflating means. The balloon is arranged at the tip of the catheter at one side thereof so as to press the opposite side of the catheter against the wall of the rectum and thus to fix the catheter in position. By means of a reflector, microwave energy is directed preferentially in the direction opposite to the balloon

towards the prostate. No compression of prostate tissue is foreseen.

The subject-matter of claim 1 on file differs from the rectal catheter known from D1 in that the inflatable balloon surrounds the microwave antenna and is designed to be inflated so as to exert squeezing pressure on the prostate and intermediate non-prostate tissue.

- 4.3 From document D6 (see in particular Figure 1 with the corresponding description) a generic endotract catheter for hyperthermia treatment by microwave heating of lesions on organs inside the body is known, which comprises an inflatable balloon surrounding the microwave antenna. The balloon and the microwave antenna are both situated at the tip of the catheter. The catheter is not specifically adapted for a treatment of the prostate via the rectum, as the microwave antenna is designed to apply a substantially uniform angular distribution of microwave field intensity to the surrounding tissue. The balloon is formed so as to come in its inflated state in close contact with the wall of the organ tract where the lesion is located so that a chamber of variable volume is formed around the microwave antenna and no gases or fluids remain in the gap between the antenna and the surface of the organ (column 1, lines 24-28 and 65-68; column 2, lines 54-57). In order to allow the balloon to be inflated into intimate contact with the wall of the tract or lumen organ, it is made from a thin, highly flexible polymeric film (column 2, lines 57-62; column 3, lines 26-29; column 4, lines 4-17). The inflated balloon should comply with an uneven inner

profile of the wall of the organ, but no compression of the surrounding tissue is intended.

The catheter according to present claim 1 differs in essence from the known catheter in that it is specifically adapted to be inserted into a male patient's rectum, that the inflatable balloon and the microwave antenna are situated at a distance from the tip of the catheter, that the catheter comprises distribution means for providing a distribution of microwave field intensity preferentially in a direction towards the prostate, and that the inflating means are configured to inflate the balloon to a cross-section larger than the cross-section of the rectum so as to squeeze and compress the surrounding tissue including that of the prostate.

4.4 Thus neither D1 nor D6 shows a rectal catheter comprising all features specified in claim 1 under consideration.

Moreover, none of the further documents referred to in the contested decision or cited in examination or in the International and European Search Reports discloses a rectal catheter for treating prostate diseases which possesses in combination microwave antenna means for preferential irradiation of the prostate and an inflatable balloon designed for squeezing and compressing the heated tissue.

Consequently, the subject-matter of claim 1 has to be regarded as novel over the available state of the art. The same applies to independent claim 6 directed to an

arrangement of a rectal catheter as specified in claim 1 and a urethra catheter.

- 4.5 According to additional remarks added to the contested decision, the examining division considered a rectal catheter as disclosed by the application to be rendered obvious by a combination of the teachings of documents D1 and D6.

Apart from the facts that, in these remarks, the division does not particularly pay attention to the different functions served by the respective inflatable balloons according to D1, D6 and the present application and that it leaves all functional features out of consideration which relate to a squeezing and compression of tissue by the inflated balloon and to an increase in distance between the microwave antenna and the heated tissue, the division's analysis is apparently based on the opinion that claimed features missing from one of the documents are known from the other document and so conventional that they are arbitrarily interchangeable.

The Board is aware of the fact that the features distinguishing the claimed subject-matter from a catheter as known from either D1 or D6 are at least in part known from the other document and, moreover, were known as such before the international filing date of the present application for one type of catheter or another, as is apparent from documents cited in the search reports for the present application. For instance, a catheter comprising an inflatable balloon surrounding an antenna for microwave heating of tissue was used for the treatment of stenoses in blood

vessels. More specifically, as regards the treatment of an enlarged prostate by means of a urethra catheter, it was known to use a balloon catheter for mechanically widening the urethra so as to remove a stenosis or to use a catheter with a microwave antenna for a hyperthermia treatment.

However, regarding the issue of inventive step, the decisive question to be answered is whether the skilled person would have applied such measures to a rectal catheter and would have accordingly modified a catheter as known from D1 or D6.

Unlike the situations encountered for treating the prostate by means of a urethra catheter or for a dilation treatment of stenoses in blood vessels, a treatment of the prostate from the side of the rectum does not require the widening of a stenosis. Therefore, the Board sees no incentive for the skilled person to purposefully modify a catheter as known from D1 or D6 so as to arrive at a rectal catheter for hyperthermia treatment of the prostate as defined in claim 1 under consideration having inflatable means for increasing the distance between the microwave antenna and the heated tissue. As a matter of fact, none of the available prior art documents hints at the idea to improve hyperthermia treatment of the prostate by means of a rectal catheter by squeezing and compressing the heated tissue so as to render the heating more homogeneous and increase the efficiency of heating diseased tissue without exceeding safe temperature limits for healthy tissue.

For these reasons, the Board considers the subject-matter of claims 1 and 6 to involve an inventive step within the meaning of Article 56 EPC.

Claims 2 to 5 and 7 to 11 are dependent claims and, therefore, their subject-matters also comply with Article 56 EPC.

5. In the result, the Board finds that the appellant's request satisfies 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 with the order to grant a patent on the basis of the appellant's request filed during the oral proceedings of 10 February 2004.

The Registrar:

The Chairman:

R. Schumacher

G. Davies