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**Datasheet for the decision
of 27 July 2007**

Case Number: T 0634/02 - 3.4.01

Application Number: 91113481.5

Publication Number: 0459535

IPC: A61N 5/02

Language of the proceedings: EN

Title of invention:

Apparatus for the surgical treatment of tissues by hyperthermia, preferably the prostate, with cooling means

Applicant:

UROLOGIX, INC.

Opponent:

-

Headword:

Apparatus for the surgical treatment of tissues by hyperthermia with cooling means

Relevant legal provisions:

EPC Art. 76(1), 123(2), 54(1)(2), 56

Keyword:

"Added subject-matter (no, after amendment)"

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

Decisions cited:

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Catchword:

-



Case Number: T 0634/02 - 3.4.01

D E C I S I O N
of the Technical Board of Appeal 3.4.01
of 27 July 2007

Appellant:

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Decision under appeal:

Decision of the Examining Division of the
European Patent Office posted 14 January 2002
refusing European application No. 91113481.5
pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: B. Schachenmann
Members: H. Wolfrum
G. Assi

Summary of Facts and Submissions

I. Present European patent application No 91 113 481.5 (publication No. 0 459 535) is a divisional application from earlier European patent application No 89 403 199.6 (publication number 0 370 890).

The application was refused by a decision of the examining division dispatched on 14 January 2002 for the reason of infringement of the requirements of Article 76(1) EPC by the subject-matter of independent claim 1.

The examining division additionally noted that the subject-matter of claim 1 lacked an inventive step within the meaning of Article 56 EPC.

II. On 14 March 2002 the applicant lodged an appeal against the decision and paid the prescribed fee. On 21 May 2002 a statement of grounds of appeal was filed.

III. The following prior art documents were considered pertinent in the proceedings of the present application:

- D1 : EP-A-0 248 758;
- D4 : "Medical Tribune", 31 March 1988, pages 3, 13 and 14;
- D5 : T. Harada et al: "Microwave surgical treatment of diseases of prostate"; Urology, December 1985, vol. XXVI, no. 6, pages 572 to 576;
- D10 : DE-A-24 07 559;
- D11 : G. Biffi Gentili et al: "Two-element radiating system for endocavitary

hyperthermia"; Hyperthermic Oncology 1988, Proceedings of the 5th International Symposium on Hyperthermic Oncology; Kyoto, Japan, 29 August - 3 September 1988; vol. 1, summary papers, pages 904 and 905; and

D12 : US-A-4 375 220.

IV. On 14 March 2006 oral proceedings were held on the appellant's request.

As a result of the discussion, the appellant requested that the decision under appeal be set aside and a patent be granted on the basis of the following documents:

claims: 1 to 19 filed in the oral proceedings;
description: pages 1 and 2 of European patent application
No 91 113 481 as filed;
pages 3, 3a and 4 to 14 filed in the oral proceedings;
drawings: Figure 1 filed on 18 June 1996;
Figures 2, 2a and 3 to 7 of European patent application
No 91 113 481 as filed.

V. In view of the fact that some of the dependent claims filed with the divisional application comprised subject-matter extending beyond the content of the earlier application as filed and thus required corresponding amendment, the Board stayed its final decision until the Enlarged Board of Appeal decided in case G 1/05 whether such amendments are possible under the provision of Article 76(1) EPC. The debate with

respect to the patentability of claim 1 filed in the oral proceedings was closed at the end of the oral proceedings.

VI. Independent claim 1 of the earlier application No 89 403 199 reads as follows:

"1. Apparatus for the surgical treatment of tissues (12) by hyperthermia, preferably the prostate (14), of the type equipped with heating means (16) for inducing hyperthermia, comprising a microwave generating device (18) placed in an emitting probe means (20) adapted to be inserted in a cavity of the body, characterized in that means (22, 90) are provided for protecting from the heat the sensitive tissues other than the tissues (12) to be treated, said means preferably comprising means forming radioreflecting screen (22,90)."

VII. Independent claim 1 of the appellant's present request reads as follows:

"1. Apparatus for the surgical treatment of prostatic tissues by hyperthermia, comprising a rectal probe (82) provided with temperature sensing means (98) and an urethral probe (20) which is adapted to be inserted in the urethra, said urethral probe having a front end (20a) and a rear end, said urethral probe (20) comprising a microwave antenna means (18) placed in said urethral probe (20) and located intermediate said front and said rear end in the vicinity of said front end (20a), said microwave antenna means (18) being connected to an external microwave generating device (M.W.G.) comprising means for generating microwaves at a frequency and a power effective for hyperthermia"

treatment, wherein said urethral probe (20) comprises cooling means (32) for cooling the surface of the urethral probe (20) in order to prevent burns from occurring on the urethral wall (34) in contact with the urethral probe (20), and wherein the urethral probe comprises the only microwave antenna means of the apparatus."

Claims 2 to 19 are dependent claims.

VIII. In its decision, the examining division considered the *"means for protecting from the heat the sensitive tissues other than the tissues to be treated"* as specified in claim 1 of the earlier application to constitute an indispensable feature of the invention as presented in the earlier application as a whole. Any claim, such as independent claim 1 of the present divisional application, which did not define this feature but instead specified *"cooling means for cooling the surface of the urethral probe means in order to prevent burns from occurring on the urethral wall"*, ie a feature which was considered to be disclosed in the earlier application as a different and optional means only, was thus held to add technical subject-matter extending beyond the content of the earlier application as filed and therefore to infringe the provision of Article 76(1) EPC.

Moreover, an apparatus comprising a urethral probe having a microwave antenna and cooling means for microwave heat treatment of the prostate was rendered obvious for instance by the teachings of documents D4 and D10.

IX. According to the appellant, it was directly and unambiguously derivable from the content of the earlier application that the cooling means as claimed in claim 1 of the divisional application was an embodiment form of the "*means for protecting sensitive tissues other than the tissues to be treated*" alternative to a radioreflecting screen mentioned optionally in claim 1 of the earlier application. It was immediately apparent from the description of the earlier application that protecting means in the form of radioreflecting screens and cooling means independently from each other protected from the heat different types of tissues at different locations from the urethral probe, eg the tissue of the bladder or the sphincter in case of the screens and the wall of the urethra in direct contact with the probe in case of the cooling means, so that both fell under the same category of tissue protecting means within the meaning of the definition of claim 1 of the earlier application.

With respect to the issue of inventive step, the appellant submitted that the teachings of the available prior art documents did not motivate the skilled person to provide a urethral probe with cooling means for the purpose of preventing burns from occurring on the urethral wall.

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*

2.1 Amendments to independent claim 1 with respect to the content of the earlier application as filed (Article 76(1) EPC)

2.1.1 Independent claim 1 presently on file differs from claim 1 of the earlier application in substance in that

- (i) the apparatus is further specified to comprise a rectal probe provided with temperature sensing means;
- (ii) the emitting probe means is specified to form a urethral probe and the tissues to be treated to be prostatic tissues;
- (iii) the microwave antenna means are specified to be located in the vicinity of the front end of the urethral probe and to be the only antenna means comprised in the apparatus; and
- (iv) instead of the apparatus being provided with means for protecting from the heat the sensitive tissues other than the tissues to be treated, the urethral probe is defined to comprise cooling means for cooling the surface of the urethral probe in order to prevent burns from occurring on the urethral wall in contact with the urethral probe.

2.1.2 In the Board's view, amendments (i) to (iii) clearly comply with the provision of Article 76(1) EPC. Reference is made in particular to the following pieces of disclosure in the documents of the earlier application as filed:

feature (i) is disclosed by the subject-matter of claim 12; the features under (ii) have a basis of disclosure in claim 4 of the earlier application and

are common to all specific embodiments; and the features under (iii) are directly derivable from Figures 1 to 3 and the corresponding description (cf in particular column 7, lines 47 to 58 of the published earlier application).

2.1.3 More critical is indeed the question of disclosure of amendment (iv) in the documents of the earlier application, and in particular the question whether the deletion from claim 1 of the "*means for protecting sensitive tissues other than the tissues to be treated*" and the replacement of this feature by the definition of cooling means forming part of the urethral probe has to be regarded as an inadmissible omission of a feature forming part of the definition of the claimed invention in the earlier application.

2.1.4 As far as the claims are concerned which were originally filed in the earlier application, cooling means are specified in dependent claim 11, which reads:

"11. *Apparatus as claimed in one of claims 1 to 10, characterized in that means (32) are provided for cooling the surface of the the [sic] probe means (20) in order to prevent burns from occurring on the walls in contact with the probe means, particularly the walls of the urethra (34).*"

Apparently, in defining the cooling means (32) to prevent burns from occurring, the wording of claim 11 does not make any reference to the means (22, 90) for protecting sensitive tissue as specified in claim 1. Thus, on the basis of a strictly linguistic reading of claims 1 and 11, it would have to be concluded that the

cooling means do not represent or form part of the means for protecting sensitive tissue and that the two means refer to different items.

2.1.5 As regards the description and drawings of the earlier application as filed, the presentation of the invention in the chapter "summary" sets out with listing a variety of objects of the invention and continues by presenting means for protecting from the heat sensitive tissues other than the tissues to be treated as the inventive solution. What follows are a reference to radioreflecting screen means as a particularly preferred embodiment of such protecting means and a presentation of various examples of such screen means. In this context, no alternative embodiment to screen means is mentioned. The summary continues with a reference to other advantageous embodiments of the invention which are technically unrelated to the protecting means, such as positioning control means or immobilizing means (cf. column 4, lines 15 to 31, of the published earlier application). Only thereafter (*ibid.* column 4, lines 32 to 37) reference is made to cooling means, which, although being also introduced as "*another advantageous embodiment of the invention*", are not presented as an alternative to the previously discussed protecting means.

A similar presentation of the invention is given by the description of the preferred embodiments: in column 6, line 29 to column 7, line 5, of the published earlier application a description of embodiments of the protecting means is followed by a reference to cooling means as an advantageous embodiment of the emitting

probe means but not as an embodiment of the protecting means.

Contrary to the opinion of the appellant (see page 4, fourth paragraph of the grounds of appeal), the parent application does not show any specific embodiment without radioreflecting screen means. Even Figures 5 to 7, showing variants of the cooling ducts, show them in combination with screen means (see the indication of the separate ducts 229, 329, 429, respectively, for a radioreflecting liquid).

It is furthermore apparent from the application documents that the cooling means prevent the urethral wall from being burnt but are unable to protect any of the tissues protected by the specifically disclosed protecting means (ie the bladder, sphincter or rectal wall), which, on the other hand, cannot protect the urethral wall from being heated.

2.1.6 In view of the above observations, the Board considers a reader to gather from the originally-filed documents of the earlier application the following pieces of information:

- The provision of means for protecting from the heat sensitive tissues other than the tissues to be treated is an indispensable feature of the invention, without which the objects of the invention would not be achieved.
- The specifically discussed examples of the protecting means are radioreflecting screen means.
- The cooling means are not described or defined as an embodiment of the means for protecting tissues from the heat (as a matter of fact, the two means are

consistently presented throughout the description and the originally-filed claims as unrelated features).

- The radioreflecting screen means and the cooling means provide protection to different types of tissues at different locations.

2.1.7 However, the Board agrees with the appellant that the documents of the earlier application do not apply to a linguist but to the skilled person in the field of heat therapy of the prostate, *ie* to an urologist cooperating with an electrical engineer or physicist. Thus independently from what the person drafting the documents of the earlier application may have perceived as protecting means, in the Board's view, the skilled reader of these documents would not only immediately realise that radioreflecting screen means are but one example of means for protecting sensitive tissues other than the tissues to be treated but that the disclosed cooling means provide protection for tissues not to be treated as well, independently of the presence of any radioreflecting screen means. In this context, the skilled person would readily comprehend that if the tissue of the urethral wall needed to be protected from being burnt the only protecting means disclosed are constituted by the cooling means.

Consequently, all things considered and notwithstanding the fact that the Board understands the line of reasoning given by the examining division, the Board has come to the conclusion that the skilled reader of the earlier application would directly and unambiguously perceive the cooling means as an example of means protecting from the heat sensitive tissues other than the tissues to be treated. Therefore,

replacing the definition of the latter by that of the former, as by aforementioned amendment (iv), is not considered to constitute an omission of an essential feature from an originally filed independent claim but a replacement of a generic definition by a more specific one.

2.1.8 For these reasons, the Board is satisfied that claim 1 on file does not introduce subject-matter beyond the content of the earlier application and therefore complies with the provision of Article 76(1).

2.2 Amendments to independent claim 1 with respect to the content of the divisional application as filed (Article 123(2) EPC)

Claim 1 in its present version differs from the version of the divisional application as filed by amendment (i) listed in point 2.1.1 above and the specification that the microwave antenna means constitutes the only antenna means comprised in the apparatus.

Feature (i) is disclosed by the subject-matter of claim 11 of the divisional application as filed and the second amendment is directly derivable from Figure 1 and the corresponding description.

Therefore, claim 1 on file also complies with the provision of Article 123(2) EPC.

2.3 Dependent claims

2.3.1 The additional feature specified in claim 2 is disclosed in column 7, lines 12 to 18, of the earlier

application, corresponding to column 7, lines 32 to 38, of the divisional application as filed.

The additional features according to claim 3 are disclosed in column 6, lines 56 to column 7, line 2, of the earlier application, corresponding to column 7, lines 18 to 22, of the divisional application as filed.

Claims 4 and 10 define alternative options specified in claim 12 of the earlier application and correspond to claims 5 and 11 of the divisional application as filed.

The additional features according to claim 5 are disclosed in column 7, lines 47 to 55, of the earlier application, corresponding to column 8, lines 9 to 17, of the divisional application as filed.

The additional features according to claims 6 and 7 define alternative options specified in claim 7 of the earlier application and correspond to claims 7 and 8 of the divisional application as filed.

Claims 8, 9, 11, 13 and 14 correspond to claims 9, 10, 15, 2 and 3, respectively, of the earlier application and claims 9, 10, 12, 14 and 15, respectively, of the divisional application as filed.

Claim 12 defines an option included in claim 1 of the earlier application and corresponds to claim 13 of the divisional application as filed.

The additional features according to claim 15 are disclosed in column 11, lines 46 to 49, of the earlier

application, corresponding to column 11, lines 29 to 32, of the divisional application as filed.

The additional feature according to claim 16 is disclosed in column 7, line 58 to column 8, line 3, of the earlier application, corresponding to column 8, lines 20 to 23, of the divisional application as filed.

The additional features according to claim 17 are disclosed in column 9, lines 37 to 44, of the earlier application, corresponding to column 9, lines 50 to 58, of the divisional application as filed.

The additional features according to claim 18 are disclosed in column 9, line 45 to column 10, line 2, of the earlier application, corresponding to column 10, lines 1 to 16, of the divisional application as filed.

The additional feature according to claim 19 is disclosed in column 10, lines 2 to 6, of the earlier application, corresponding to column 10, lines 16 to 20, of the divisional application as filed.

2.3.2 The Board is thus satisfied that, after amendment, the subject-matter of the dependent claims has a proper basis of disclosure in the documents of the earlier application as well as in those of the divisional application as filed.

3. *Novelty and inventive step (Articles 52(1), 54(1) and (2) and 56 EPC)*

3.1 None of the available documents of the prior art shows an apparatus for the surgical treatment of prostatic

tissues by hyperthermia through microwave absorption, comprising in combination a urethral probe and a rectal probe, wherein the urethral probe comprises, in addition to the only microwave antenna means of the apparatus, cooling means for cooling the surface of the urethral probe in order to prevent burns from occurring on the urethral wall.

Thus the subject-matter of claim 1 is novel within the meaning of Articles 54(1) and (2) EPC.

3.2 The documents which played a role in the examination and appeal proceedings form two groups, of which the first group comprises documents D4, D5 and D11 relating specifically to urethral probes, whereas the second group comprises documents D1, D10 and D12 concerning other probes for heat treatment by microwaves.

3.3 From the first group of documents, document D4 (see the whole document) concerns a conventional transurethral catheter which is retrofitted with three microwave antennas being equidistantly arranged around its periphery so as to allow transurethral hyperthermia of benign prostatic hyperplasia (BPH) as an alternative to surgical resection of enlarged glandular tissue. A central portion of the prostate is heated by means of microwaves to a temperature of 45 °C. The treatment, which extends over a period of several weeks, results in a gradual shrinkage of the irradiated tissue. It is acknowledged that a limiting factor to the advancement of the therapy is equipment that can produce the kind of controllable temperature elevations that are required for treatment.

Document D5 (see in particular page 572 and Figure 1) describes a urethral probe having a coaxially arranged microwave antenna for surgical treatment of diseases of the prostate, such as BPH or carcinoma. The microwave irradiation of the prostate is performed at a power level of up to 100 W with the intention to cause heat coagulation and necrosis of prostatic tissue. No cooling of the urethral probe is foreseen.

3.4 Document D11 presents considerations relating to a hyperthermia treatment of the prostate by means of an apparatus having in combination a rectal probe as a primary probe and a urethral probe as a secondary probe and discusses preliminary measurements of specific absorption rates using either both probes or only the primary probe. In the experiments, both probes comprise a microwave antenna as well as an external cooling system. D11 does not fully disclose the structure of the probes and is silent in particular as to the arrangement and purpose of the external cooling system. Moreover, it is mentioned that the clinical feasibility of the contemplated approach necessitates solutions to thermodynamic and design problems concerning the urethral antenna.

3.5 Documents D1 (see in particular pages 2 to 4; page 5, second paragraph; and page 8, lines 19 to 23), D10 (see the description) and D12 (see in particular Figures 4 and 5) each relate to microwave emitting probes to be inserted into body openings for localised hyperthermia treatments. Each of the known probes comprises a coaxially arranged microwave antenna. In order to predominantly heat tissues which are located at a distance from the probe and to avoid at the same time a

heating of tissues which are in immediate contact with the surface of the probe, the probe comprises cooling means for efficiently cooling its surface. The position of the region of maximal temperature can be shifted within the tissue away from the surface of the probe by varying the ratio of heating and cooling.

The specific embodiment of document D1 relates to a rectal probe. Documents D10 and D12 show examples of straight probes. Moreover, D12 shows probes specifically shaped to treat cancer of the nasopharynx, oral pharynx and throat.

- 3.6 In view of the general task to devise an apparatus for heat treatment of prostatic tissue, any of documents D4, D5 or D11 can be taken as a starting point for an inventive step consideration.

In this respect, the appellant argued in essence that none of these documents provided a motivation for the skilled person to contemplate a thermal treatment of the prostate which exclusively took place through the urethra and efficiently destroyed prostatic tissue without sacrificing the urethra.

Document D4 concerned a urethral probe causing only a modest heating of prostatic tissue which resulted in a gradual shrinkage of the irradiated tissue over a treatment period of several weeks. The known treatment thus did not cause burns of the urethral wall so that there was no incentive for the skilled person to contemplate any measures for avoiding such burns.

Document D5 set out from conventional open surgery or transurethral resection of the prostate implying inter alia the risks of hemorrhage and anesthetic complications and offered transurethral microwave treatment of the prostate with significant destruction of prostatic tissue with minimised bleeding due to heat coagulation of the irradiated tissue. The purpose of the microwave treatment was to mimic mechanical surgery by electromagnetic means. Thus D5 constituted evidence for the conventional wisdom of an urologist at the priority date of the present application namely that treatment of the prostate be it by conventional surgery or by microwave heating implied sacrificing the urethra. The teaching of D5 did not incite the skilled person to act otherwise.

Finally, document D11 contemplated microwave treatment of the prostate primarily by means of a rectal probe. Moreover, although the document mentioned an external cooling system also for the urethral probe, no indication was given that such cooling means should be capable of cooling the surface of the probe in order to prevent burns from occurring on the urethral wall.

- 3.7 In the absence of any indication in the available prior art which would have incited the skilled person to contemplate a surgical treatment of the prostate without sacrificing the urethra and thus of any pointer linking the teachings of the aforementioned two groups documents, the Board accepts the appellant's argumentation that the subject-matter of claim 1 on file is not rendered obvious by any combination of the available prior art documents.

The Board sees its judgment confirmed by the circumstance that although probes for microwave treatment by hyperthermia adapted to be inserted into a variety of body openings or ducts and equipped with cooling means had been around for several years - D10 for instance was published some 13 years before the priority date of the present application - apparently nobody concerned with the treatment of prostatic tissues considered it worthwhile to cool the surface of a microwave urethral probe in order to preserve the urethra.

- 3.8 For these reasons, the Board considers the subject-matter of claim 1 on file to involve an inventive step within the meaning of Article 56 EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the examining division with the order to grant a patent on the basis of the following application documents:
 - claims: 1 to 19 filed in the oral proceedings;
 - description: pages 1 and 2 of European patent application
No 91 113 481 as filed;
pages 3, 3a and 4 to 14 filed in the oral proceedings;
 - drawings: Figure 1 filed on 18 June 1996;
Figures 2, 2a and 3 to 7 of European patent application
No 91 113 481 as filed

The Registrar

The Chairman

R. Schumacher

B. Schachenmann