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D E C I S I O N
of 17 October 1994

Case Number: T 0240/93 - 3.4.1

Application Number: 89403199.6

Publication Number: 0370890

IPC: A61N 5/04

Language of the proceedings: EN

Title of invention:

Apparatus for the surgical treatment of tissues by hyperthermia, preferably the prostate, equipped with heat protection means preferably comprising means forming radioreflecting screen

Applicant:

TECHNOMED INTERNATIONAL

Opponent:

-

Headword:

-

Relevant legal provisions:

EPC Art. 56

Keyword:

"Inventive step (yes)"

"Apparatus based on a non-obvious therapeutical concept"

"Supposed bonus effect is in view of practical importance crucial to the invention and basis of the objective problem. (para. 3.2)"

Decisions cited:

-

Catchword:

-



Case Number: T 0240/93 - 3.4.1

D E C I S I O N
of the Technical Board of Appeal 3.4.1
of 17 October 1994

Appellant:

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Decision under appeal:

Decision of the Examining Division of the European
Patent Office dated 2 November 1992 refusing
European patent application No. 89 403 199.6
pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: G. D. Paterson
Members: H. J. Reich
R. K. Shukla

Summary of Facts and Submissions

I. European patent application No. 89 403 199.6 (publication No. 0 370 890) was refused by a decision of the Examining Division.

II. The reason given for the refusal was that the subject-matter of Claims 1 of the main and auxiliary requests filed at the oral proceedings on 14 October 1992 did not satisfy the requirements of Articles 52 and 56 EPC having regard to documents:

D1: EP-A-0 248 758,

D4: "Medical Tribune", 31 March 1988, pages 3, 13 and 14, and

D5: "Urology", December 1985, vol. XXVI, no. 6, pages 572 to 576, and

taking into account the general knowledge of the skilled person at the priority date, as exemplified by documents:

D6: "Journal of Microwave Power", vol. 17, no. 3, 1982, pages 203 to 209,

D7: WO-A-81/03616,

D8: "The Prostate" vol. 8, 1986, pages 93 to 102, and

D9: T. H. Schiebler et al. "Lehrbuch der gesamten Anatomie des Menschen" Springer Verlag, Berlin, Heidelberg, New York and Tokyo, 3 Aufl., 1983, pages 550 to 581.

The above evidence includes some of the documents which were filed under Article 115 EPC by third parties.

The Examining Division took the following view: A skilled person knows that the fibromuscular nodules in the lateral lobes of the prostate are responsible for benign prostate hyperplasia (BPH). Since there is a priori no reason to destroy the urethral wall, it would be obvious to avoid this negative side-effect produced in the known BPH treatment using the conventional urethral probes disclosed in documents D4 to D5, to preserve healthy tissue as far as possible and to concentrate heat on the lateral lobes of the prostate, following the principle that it is generally desirable to remove the cause of a disease. Document D1 teaches that an applicator with a central linear antenna and cooled surface may be used for heating remotely-located tissue without undue heating of the tissue in direct contact with the applicator. The distance between the antenna and the tissue to be heated in the rectal treatment method compares with that between the urethra and the outermost BPH tissue. Hence, a skilled person would consider the closely related field of hyperthermia rectal probes, apply the cooling means disclosed in document D1 in a device according to document D4 and thus arrive at the subject-matter of Claim 1 of each of the main and auxiliary requests. There would have been no technical prejudice against preserving the urethral wall since it does not contribute to the obstruction of the urethral passage. The short treatment duration of one hour and further advantages resulting from the use of cooling means are considered as extra (bonus) effects. According to decision T 21/81 (OJ EPO 1983, 15) the subject-matter of a claim resulting from an obvious combination of prior art documents lacks an inventive step regardless of the fact that such extra unforeseen effects are obtained.

III. The Applicant lodged an appeal against this decision.

IV. In his submissions in the Statement of Grounds of Appeal and in his letters dated 3 August 1994, 15 September 1994 and 19 September 1994, the Appellant based his arguments concerning the existence of an inventive step underlying the subject-matter of the independent Claims on the following evidence:

- 1°. Doctor Jonas' declaration of 15 April 1991
- 2°. Declaration of Doctor Devonec, one of the inventors
- 3°. Declaration of Doctor Blute of the Mayo Clinic of Rochester, USA
- 4°. Declaration of Professor Lynch of the Georgetown University Medical Center, Washington D.C., USA
- 5°. Declaration of Professor Debruyne of the University Hospital Nijmegen, The Netherlands
- 6°. Declaration of Doctor REGAN of the Georgetown University Medical Center, Assistant Professor of Surgery
- 7°. Declaration of Doctor Carter of the Charing Cross Hospital, London, the United-Kingdom
- 8°. Declaration of Doctor Perez-Castro of Clinica La Luz, Madrid, Spain and its English translation
- 9°. Declaration of Doctor Tobarro of Universita'Degli Studi - L'Aquila, Milano, Italy
- 10°. Abstract from the Urology Seminar in Singapore, 18 April 1992
- 11°. WHO's report on BPH by Perez-Castro et al., Arch. Esp. de Urol., 41.1, 1992, pages 1 to 19
- 12°. BSD's European patent application EP-A-0 462 302
- 13°. Japanese patent application 3-12174 and its partial English version
- 14°. Japanese patent application 2-121675 and its partial English translation
- 15°. Japanese patent application 2-121676 and its English translation
- 16°. Japanese patent application 2-121677 and its partial English translation

- 17°. European patent application EP-A-0 449 472 ARGOMED
- 18°. Preliminary information, commercial brochure of the applicant on "Prostatron", distributed at the beginning of 1990
- 19°. Complete "Prostatron" commercial brochure available from 1991
- 20°. Mr Lacoste's declaration, Research and Development manager of TECHNOMED INTERNATIONAL
- 21°. Mr Février's declaration, Administrating and Financial Manager of TECHNOMED INTERNATIONAL
- 22°. Copy of page 253 of the World Book of Inventions reporting thermotherapy and Prostatron.
- 23°. HARADA's article in Japanese and its English translation
24. Electratha's letter dated 14 April 1992 and BRUKER SPECTROSPIN'S letter dated 21 January 1992 (document 24a)
- 25°. Two drawings of basic prostate resection techniques
- 26°. "Compte Rendu de Congres", vol. 26, No. 3, 1992, page 189
- 27°. Castanena's article in Journal of Endourology, vol. 5, No. 2, 1991, pages 123 to 127
- 28°. Jonas' declaration of 18 February 1993
- 29°. BSD Medical Corporation's patent application PCT WO92/07622
- 30°. Two figures demonstrating heated and shrunk areas of a prostate according to document D4.

V. Furthermore, the Appellant cited prior art documents (D10 to D29) which had come to his attention in the proceedings before patent offices other than the EPO, and requested in his letter dated 3 August 1994 that the Board should take into account this further prior art.

VI. Oral proceedings were held on 17 October 1994, at the end of which the Appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the following text:

Main request: (as filed during the oral proceedings of 17 October 1994);

Claims: 1 to 24, filed on 17 October 1994;

Description: Columns 1 to 4, filed 17 October 1994, columns 5 to 11 as in EP-A-0 370 890;

Drawings: Figure 1 to 7 as in EP-A-0 370 890.

First, second and third auxiliary requests as filed on 19 September 1994.

Claim 1 of the **main request** reads as follows:

"1. Apparatus for the surgical treatment of prostate tissues by hyperthermia, comprising a heating probe constituted by an urethral microwave emitting probe (20) which is adapted to be inserted in the urethra, said emitting probe (20) having a front end (20a) and a rear end, said emitting probe (20) comprising a microwave antenna means (18) placed in said emitting probe (20) and located intermediate said front end and said rear end in the vicinity of said front end (20a), said microwave antenna means (18) emitting microwaves in all directions and being connected to an external microwaves generating device (MWG) comprising means for generating microwaves at a frequency and a power effective for hyperthermia treatment,

characterized in that said urethral probe (20) comprises a single microwave antenna means (18) located substantially axially in said urethral emitting probe, cooling means (32) being provided in said urethral probe (20) around said axial microwave antenna means (18) for cooling the surface of the urethral probe (20) facing

said single microwave antenna means (18), said cooling means being fed with a cooling fluid, said emission of microwaves being adapted to said cooling fluid to prevent burns from occurring on the prostrate urethral wall (34) in contact with the probe (20)."

Claims 2 to 24 are dependent on Claim 1.

VII. In support of these requests the Appellant submitted essentially the following arguments:

- (a) The closest prior art disclosed in document D4 describes a transurethral applicator for benign prostatic hyperplasia (BPH) treatment by hyperthermia, having the features of the pre-characterising part of Claim 1. The applicator consists basically of a hollow Folley-catheter with three angularly displaced antennas on its outside. Its uncooled probe surface heats the central portion of the prostate gland at 45°C and thus causes necrosis of the urethral wall and the neighbouring prostate tissue. According to document D4, a five-week course of treatment with hyperthermia delivered once or twice weekly was necessary. Using the apparatus claimed in Claim 1, the treatment reduces to one out-patient treatment of normally one hour without burns on the prostatic urethra; see also evidence No. 4° and 24°.
- (b) The Applicant has thus put forward a new technical problem of therapeutic treatment for destroying prostate tissues by heat through an urethral route in a short total duration treatment while preserving the urethral wall. Formulation of a new problem may indicate the presence of an inventive step according to the case law established in

unpublished decisions T 813/90 and T 903/91.

Unobviousness of this problem is further supported by evidence No. 28°.

- (c) This problem is solved by the combination of the features claimed in the characterising part of Claim 1, specifying **one** centrally located axial antenna surrounded by cooling means. An analysis of inventive step based on an argument that the use of a centrally located antenna surrounded by a coolant, as in the transrectal applicator, in an transurethral probe would be obvious, is based on hindsight. Such an analysis does not take into account that a therapeutical purpose is a prerequisite to the finding of a technical solution; see also the decision of the Bundespatentgericht in the nullity action against German patent 3 146 628, dated 24 January 1990. Moreover, in the case of unusual methods where efficacy depends on a variety of circumstances, successful therapeutic effects can scarcely be regarded as foreseeable, especially if they are produced only by a modification of the technical means applied. This offers - following decision T 268/89 OJ EPO 1994, 50 - in the present case sufficient indication for the existence of an inventive step; see also evidence No. 29°.

- (d) Since in the transurethral treatment of BPH known, for example from documents D4 and D5, no importance is attached to the preservation of the urethral wall, there existed a therapeutical prejudice in the art against the preservation of the urethral wall. The urethral wall (mucosa) is extremely thin, of the order of some micrometers, so that it is impossible to preserve the urethral wall without also preserving ill tissue of the lateral lobes of

the prostate. Moreover, it was known that destruction of the urethra due to excessive heating causes sloughing of the prostate, chronic discharge of purulent material and clinical complications (see evidence No 7°, point 6). Though the technical means for cooling the surface of a microwave heating probe were known for more than 10 years, no cooling was applied in the urethral probes disclosed in documents D4 and D5.

- (e) Although document D1 discloses a rectal probe provided with cooling means, there is no disclosure that the cooling would enable a shortened treatment. On the contrary, evidence No. 11° shows that the corresponding apparatus with a rectal probe required multiple heat sessions identical to those recognised by document D4.

VIII. At the conclusion of the oral proceedings, the decision was announced that the decision of the Examining Division is set aside and that the case is remitted to the first instance with the order to grant a patent in accordance with the main request filed on 17 October 1994 (see paragraph VI above).

Reasons for the Decision

1. Claim 1 of the main request comprises the subject-matter of original Claims 1, 4 and 11 and features disclosed in Figures 1 and 2 and the corresponding description in particular page 9, lines 28 to 34 and page 12, lines 8 to 24. In addition to the subject-matter of Claim 1 forming the basis of the decision under appeal present Claim 1 includes subject-matter specifying that the microwave antenna means are "a single microwave antenna

means located substantially axially in said urethral probe", that the cooling means are provided "around said axial microwave antenna means facing said single microwave antenna means". Claims 3 to 15 contain features of original Claims 5, 2, 12, 13, 7, 7, 9, 10, 12, 15, 1, 2 and 3 respectively. Claims 16 to 19, 23 and 24 are directed to features respectively disclosed in the following parts of the original description: page 14, lines 23 to 26; page 11, lines 31 to page 12, line 1; page 12, lines 2 to 14; page 12, lines 14 to 17; page 14, lines 22 and 23; and page 12, lines 8 to 14 in combination with page 14, lines 22 and 23. The features in Claims 2, 20 to 22 are derivable from Figure 2 and 5 to 7 respectively. The amendments of the description are in line with Rules 27(1)(b), (c) EPC. There is therefore no objection under Article 123(2) EPC to the current set of application documents.

2. Document D4 describes an apparatus with a urethral microwave emitting probe adapted to be inserted in the urethra, comprising only the features defined by the wording of the pre-characterising part of Claim 1. Such a urethral probe is also described in document D5. The urethral microwave emitting probes disclosed in documents D4 and D5 are in particular not provided with cooling means. The cooling means of the urethral microwave emitting probe disclosed in the Summary Papers of the 5th International Symposium on Hyperthermic Oncology, Kyoto, Japan, 29 August to 3 September 1988, vol. 1, pages 904, 905 and Figures 1 to 6 (D11) feed only the stub portion of the probe and are not provided **"around** said axial microwave antenna means and **facing** said microwave antenna means", so that the probe surface in the microwave emitting region of the antenna remains uncooled. The microwave emitting probes disclosed in the further prior art documents on file do not come nearer

to the invention than documents D4 and D5. Thus, the subject of Claim 1 of the **main request** is considered to be new in the sense of Article 54 EPC.

3. *Inventive step - Claim 1 - main request*

3.1 Starting from the closest prior art apparatus according to document D4, the objective problem underlying the present invention is to provide an apparatus for the effective therapeutic treatment of BPH in a short period of time.

3.2 In view of the many considerable practical advantages of a single one hour hyperthermia session for a patient - including in particular the reduction of urethral irritation due to the repetitive introduction of the catheter from five to ten times reported in document D4, page 13, paragraph 7 - such a short treatment duration in the Board's view cannot be dismissed as a mere "bonus" effect, but is crucial to the objective problem - see paragraph 3.1 above.

3.3 The objective problem mentioned in paragraph 3.1 is solved by the means claimed in the characterising part of Claim 1. These technical means allow to shift the temperature maximum from the conventional central cylindrical region including the urethra into a ring shape area within a central part of the ill benign prostate hyperplasia (BPH) tissue at some distance from the urethra.

3.4 The technical means of this solution as such, i.e. cooling means around a single axially located microwave antenna, are known in heating probes which are adapted to be introduced into body cavities other than the urethra, for instance in the rectal probes disclosed in documents D1, D6 and D7. In the conventional probes

cooling is used exclusively in order to prevent burning of adjacent tissues; see for instance document D1, page 2, paragraph 2; document D7, page 6, paragraphs 1 and 2; and document D6, page 204, paragraph 1. Document D6 teaches explicitly that "less cooling will extend surface heating, whereas more cooling will shift the temperature maximum deeper into the tissue with rapidly decreasing effective power of the high frequency field". There is no statement in any one of the prior art documents which gives a hint to a skilled person that cooling would enable the treatment to be significantly shortened. In particular, the identical numbers of one hour sessions required in the uncooled transurethral BPH hyperthermia treatment and the transrectal hyperthermia treatment which applies a cooling system (see evidence no. 11°, Table 7), does not suggest to a skilled person that a cooled surface of the antenna section of a probe insertable into a body cavity would allow to reduce the duration of the treatment. In the Board's view, it is even not directly derivable from the prior art documents on file - and in particular not from Figure 3 of document D6 - to maintain the absolute value of the temperature maximum and to adapt cooling and microwave power in such a way to each other that this specific absolute temperature is simply locally shifted away from the probe surface into the interior of the tissue. However, no simple parameter transfer from the rectal route BPH hyperthermia to the urethral route one is possible. In the transrectal route the ill tissues of the prostatic zone to be heated are about 4 cm away from the probe and in the transurethral route the periurethral tissue to be destroyed is located at a distance of between a few micrometers and about 3 cm from the probe surface.

- 3.5 In the transurethral surgical resection, the prostatic urethra and the periurethral tissues are removed. This surgical concept is followed in the transurethral microwave coagulation of the prostate tissue around the urethra at 50°C and more, as disclosed in document D5. The transurethral probe disclosed in document D4 also follows the conventional surgical resection principle, since this "applicator is designed to heat the central portion of the gland that is involved in producing the patient's obstructive symptoms to a temperature of 45°C" (see document D4, page 3, the Figure and second column, second paragraph from below). Document D8, page 96, paragraph 3 reports that 1.5 hour treatment left no irreversible changes at 42.5°C and causes severe necrotic damages at 44.5°C. In the Board's view the cooled stub below the antenna dipole in the urethral probe disclosed in document D11 serves to protect the external urethral sphincter; see also D4, pages 13, second paragraph from below. Hence, the development in BPH treatment did not suggest to a skilled person to concentrate heat on the lateral lobes of the prostate or to remove the cause of the BPH disease. There is no suggestion in the prior art that instead of an approximately cylindrical necrotic tissue region surrounding the urethra, a ring-shaped necrotic region of the prostate displaced from the urethra as in the present invention would provide an effective treatment, see also paragraph II above. Thus, the development of therapeutic treatment of BPH followed another direction, even though cooling of a probe surface in its antenna region was known per se.
- 3.6 In the evaluation of inventive step it is not relevant whether a skilled person **could** have modified the hollow Folley catheter with its 3 angularly displaced axial antennas on its surface according to document D4 so as to incorporate a single antenna and cooling means as

disclosed in document D1 to arrive at the subject-matter as claimed in Claim 1. What is relevant is whether there was a clear motive for the skilled person so that he **would** have incorporated the modifications. Such a motive does not exist in the present case, since in the Board's view the basic therapeutical concept underlying the present technical invention was not obvious for the following reasons: Since the urethral mucosa has only a thickness of some micrometers, the creation of a temperature profile which restricts necrosis to the BPH tissues adjacent the mucosa while preserving the mucosa does not appear to be technically feasible. Hence, the therapeutical concept underlying the transurethral probe according to the invention maintains the enlarged periurethral tissues (also known as prostate adenoma or lateral lobes) supporting the mucosa.

The conventional transurethral resection wherein the prostate tissues causing the obstruction of the prostatic urethra are removed represents a therapeutical concept wherein the urethra cross-section is reopened and the prostatic tissues are physically removed via the urethra. Similarly, in the transurethral hyperthermia without cooling, necrosis is produced in the obstructing tissues surrounding the prostatic urethra. In the light of such prior art a person skilled in the art - in the present case a team of urologist and physicist - would not be expected to develop a new therapeutical concept wherein necrosis is produced in the centre of the lateral lobes away from the prostatic urethra with the expectation that it would relieve pressure on the prostatic urethra, which in turn would lead to an improvement in the urinary flow.

- 3.7 Moreover, the Board does not consider that a skilled person would foresee that by use of transurethral hyperthermia inter alia a shift of the maximum

temperature value from the urethral wall into the centre of the lateral lobes of the prostate, using the apparatus claimed in Claim 1, allows the treatment time to be reduced from 6 to 10 sessions of one hour to a single one hour session.

- 3.8 For the reasons set out above in paragraph 3.1 to 3.7, the subject-matter of Claim 1 is considered to involve an inventive step in the sense of Article 56 EPC. Thus, both Claim 1 and dependent Claims 2 to 24 are allowable.

Order

For these reasons it is decided that:

1. The decision of the Examining Division is set aside and the appeal is allowed.
2. The case is remitted to the first instance with the order to grant a patent in accordance with the main request filed on 17 October 1994 (see paragraph VI).

The Registrar:

The Chairman:

M. Beer

G. D. Paterson