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D E C I S I O N
of 18 April 1996

Case Number: T 0890/93 - 3.2.2

Application Number: 87304620.5

Publication Number: 0292622

IPC: A61B 17/36

Language of the proceedings: EN

Title of invention:
Vaporization contact laser probe

Applicant:
Surgical Laser Technologies, Inc.

Opponent:
-

Headword:
-

Relevant legal provisions:
EPC Art. 54(2), 56

Keyword:
"Novelty (yes)"
"Inventive step (yes)"

Decisions cited:
-

Catchword:
-



Case Number: T 0890/93 - 93 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 18 April 1996

Appellant: Surgical Laser Technologies, Inc.
1 Great Valley Parkway
Malvern
Pennsylvania 19355 (US)

Representative: Lyons, Andrew John
ROYSTONS
Tower Building
Water Street
Liverpool L3 1BA (US)

Decision under appeal: Decision of the Examining Division of the European Patent Office posted 28 May 1993 refusing European patent application No. 87 304 620.5 pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: H. J. Seidenschwarz
Members: M. Bidet
M. K. S. Aúz Castro

Summary of Facts and Submissions

- I. European patent application No. 87 304 620.5, publication No. 0 292 622, was filed on 26 May 1987.

- II. By its decision issued on 28 May 1993, the Examining Division refused the application, holding that the alleged invention was obvious in the light of documents:

WO-A-8 505 262 (D1)

WO-A-8 404 879 (D2)

GB-A-2 154 761 (D3).

The decision was based on a set of 11 claims. Claims 1 to 8 were directed to a medical laser probe in which Claim 1 read as follows:

"A medical laser probe (10) for conveying energy from the output end of an optical laser waveguide (32) to a tissue undergoing laser treatment, the probe comprising laser transmissive material having a laser energy input region for receiving laser energy from the optical waveguide and a laser energy radiation surface (11), the laser energy from the input region being propagated through the probe transmissive material to be incident on the probe radiation surface, characterised in that the laser energy radiation surface has generally a non-planar contour and in that infrared absorbing means (112) is applied on and conforming with the radiation surface for converting a predetermined percentage of the laser energy incident thereon into heat energy, whereby the increased temperature of the probe radiation surface will enhance tissue vaporisation and whereby the laser

energy the probe not converted to heat energy by the infrared absorbing means irradiates tissue adjacent the radiation surface.",

Claims 9 to 11 concerned a process for making a medical laser probe. Claim 9 read as follows:

"A process for making a medical laser surgical probe having a heat generating region thereon including the steps of taking a laser probe (10) and roughening the surface of the probe (11) which defines the nominal laser radiation region thereof; applying an infrared absorbing material (112) to the roughened surface whereby said material collects in the uneven recesses defined in the roughened surface region; and applying a protective laser transmissive coating (113) over the roughened radiation surface."

The Examining Division held that an infrared absorbing means was formed on and conformed with the radiation surface of the medical laser probe according to document D1. There was consequently more tissue vaporisation, and at the same time the laser energy not converted into heat irradiated the tissue adjacent the radiation surface. The subject-matter of Claim 1 differed from the disclosure of document D1 only in the form of the radiation surface, which on the basis of the content of document D1 and the knowledge of the skilled man, did not involve an inventive step.

IV. An appeal was filed on 27 July 1993 against that decision and the appeal fee was paid on 23 July 1993. The statement setting out the grounds of appeal, was received on 27 September 1993.

V. Following communications and consultations by telephone with the rapporteur, the appellant submitted amended Claims 1 to 11 and description, in which the independent Claims 1 and 9 have been amended to highlight more clearly the essential features of their characterising parts, that of Claim 1 reading now as follows:

"characterised in that an infrared absorbing coating (112) is applied to and conforming with the laser energy radiation surface for converting a predetermined percentage of the laser energy incident thereon into heat energy, whereby the increased temperature of the probe radiation surface will enhance tissue vaporisation and whereby the laser energy entering the probe not converted to heat energy by the infrared absorbing coating irradiates tissue adjacent the radiation surface.",

whereas in Claim 9 after the wording "laser probe 10", the words "according to Claim 1" have been inserted, the wording "applying an infrared absorbing material" has been replaced by the words "applying a coating of infrared absorbing material" and the last three words "roughened radiation surface" have been substituted by "infrared absorbing coating".

VI. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the following documents:

Claims: 1 to 11 filed with letter of 26 March 1996,
Description: pages 1 to 5, 5a, 6, 6a, 7 to 12 filed with letter of 26 March 1996,
Drawings: sheets 1/4 to 4/4 (Figures 1 to 12) filed with letter of 29 July 1987.

Reasons for the Decision

1. The appeal is admissible.
2. *Amendments*
 - 2.1 Claim 1 is based on Claim 1 of the application as filed to which have been added the features concerning:
 - (a) the infrared absorbing coating which is applied to and conforms with the laser energy radiation surface, being disclosed in the last paragraph of page 2 of the application and the Figures 2 to 6 as filed, and
 - (b) the laser energy entering the probe not converted into heat by the infrared absorbing coating which irradiates tissue adjacent the radiation surface, finding its support on page 2, lines 13 to 20 and page 8, lines 9 to 17 of the application as filed.
 - 2.2 Claim 9 has been amended to make it clear that the method permits a laser surgical probe according to Claim 1 to be obtained, and specifies in its last line that the protective laser transmissive coating is applied on the infrared-red coating as disclosed by the description as originally filed (see page 7, third paragraph and Figure 4).
 - 2.3 Claims 2 to 8 and Claims 10 and 11 correspond in their scope to Claims 2 to 8 and 10,11 of the application as originally filed, taking account of the amendments required by the new independent claims.

2.4 The description has been brought into line with the content of the new Claims 1 to 11 without adding to the disclosure of the application as filed.

2.5 The requirement of Article 123(2) EPC is therefore met by the amended document.

3. *State of the art*

3.1 Document D1 discloses a medical laser probe for conveying energy from the output end of an optical laser waveguide to a tissue undergoing laser treatment, the probe comprising laser transmissive material having a laser energy input region for receiving laser energy from the optical waveguide and a laser energy irradiation surface, the laser energy from the input region being propagated through the probe transmissive material to be incident on the probe irradiation surface (see page 3, line 32 to page 4, line 13).

The probe has a tapered portion having a laser beam emitting tip end face. According to the embodiments of the Figures 7 and 12 to 14 referred to in the decision of the examining division, the tip end face is formed of a melt of an artificial sapphire having a numerous fine bubbles therein by subjecting said tip end face to local heating.

The laser energy propagated through the tapered portion is reflected randomly by the bubbles in the melt and emitted from the surface of the melt. The melt can be formed in a spherical configuration.

It is an object of the known medical laser probe to provide a probe which is capable of effectively focusing the laser beam onto the tip end face of a rod member and irradiating the laser beam onto the tissue in contact

with the rod to make effective incision of the tissue without **any** laser energy leaking out from the tapered face of the tapered portion (see page 3, lines 15 to page 4, line 13; page 5, line 33 to page 6, line 1; page 13, line 18 to page 14, line 15; Claims 3 and 4).

The medical laser probe according to Claim 1 of the application in suit differs from that disclosed in document D1 in the features specified in the characterising portion of this Claim.

- 3.2 The medical device applying localised heat to a site in a patient's body disclosed in document D2 conveys energy from the output end of an optical laser waveguide to a heat generating element mounted with respect to the distal end of the probe such that the laser energy transmitted to the element is converted into heat to raise its temperature. This element is then brought in contact with tissues of the patients' body undergoing laser treatment to alter it.

The heat generating element is made of metal and **all** of the laser energy exiting the distal end of the optical waveguide is directed forward to be absorbed by the light receiving surface of the element. The exterior surface of the element can be coated with a non-stick or release surface to provide easy release from the patients' tissues (see page 3, line 19 to page 4, line 2; page 7, line 29 to page 8, line 35; page 10, lines 6 to 12).

The object of this known heat generating element is to provide an effective device for delivering localised heat to a site within a patient's body in order to stop bleeding or to remove body tissue or material in a blood vessel, which device is intended to overcome the

shortcomings of electrical heating means, (see page 3, lines 3 to 12).

The known device differs from the subject-matter of claim 1 according to the application in suit in that the known medical device is not designed for irradiation of the tissue by the laser energy and its heat generating element is not a coating applied on and conforming to a radiation surface.

- 3.3 Document D3 relates to a diffuse optical fibre termination for use in the phototherapy treatment of tumours and other medical conditions. The fibre is coupled to a laser beam for transmission of the laser energy to the tapered output end region of the fibre. The output end region is coated with a diffusing medium along the length of the taper and acts to scatter the emerging light (see page 1, lines 5 to 8 and lines 85 to 97; page 2, lines 93 to 99).

The stated objective for the known probe is to provide an optical termination that efficiently diffuses transmitted light and which has an emitting area sufficient to prevent baking of blood onto the termination during treatment (see page 1, lines 75 to 84).

In the device according to document D3, there is no infrared absorbing coating applied to, and conforming with the laser energy output surface. The known coating does not convert a predetermined percentage of the laser energy incident thereon into heat energy.

- 3.4 The other documents cited in the search report do not have more features in common with the subject-matter of the new Claim 1 of the application in suit than the above cited documents.

4. *Novelty*

It results from the above that there is no document disclosing in combination all the features specified in Claim 1 of the patent application.

The subject-matter of Claim 1 is therefore considered to be new within the meaning of Article 54(2) EPC.

5. *Nearest prior art*

From the above points 3.1 to 3.4, it follows that the embodiment according of document D1 represents the state of the art nearest to the invention.

6. *Inventive step*

6.1 Claim 1

6.1.1 According to the description of the application, it is an object of the invention to enhance efficiency of the contact laser irradiation system known from document D1 and therefore to reduce the laser power levels (see page 1, line 28 to page 2, line 10 of the application as filed).

6.1.2 According to Claim 1, this object is achieved by the features specified in its characterising portion.

As the infrared absorbing coating is applied to, and conforms with the laser energy radiation surface, the result is that the form of the radiation surface, the form of the face of the coating in contact with the radiation surface, and the form of the outer face of the coating, are all the same. The geometrical outside surface of the infrared absorbing coating does not alter the propagation of the laser energy through the probe.

Under these conditions, the infrared absorbing coating on the probe radiation surface absorbs a part of the laser energy as it passes from the probe. The absorbed energy, which represents only a **predetermined** part of the energy entering the probe, is accumulated into heat at the outer surface of the probe, so that the tissue in contact with the radiation surface is vaporised. Since not all the energy entering the probe is absorbed by the infrared absorbing coating, the remaining laser energy, is passed directly to the tissue adjacent the radiation surface, which is irradiated, so that the vaporisation of tissue in contact with the radiation surface of the probe is not limited to the heat generated by direct laser irradiation but includes the heat of the infrared absorbing coated radiation surface. Due the concomitant indirect heating and direct laser irradiation of the tissue, the vaporisation of the tissue is accelerated, (see page 2, lines 11 to 30 of the application as filed). This results in a better efficiency of the laser energy entering the probe which permits a reduction in the laser power levels.

6.1.3 Document D1 teaches the concentration of all the laser energy at the tip end face of the tapered portion of the probe and to irradiate tissue with substantially **all** the laser energy diffused with an angle of divergency variable according to the tapered portion. To this purpose, the melt of the end tip face is therefore transformed in such a manner that it includes bubbles. When the laser energy is propagated and concentrated through the tapered portion, it is reflected randomly by the bubbles in the melt and then irradiated from the outer surface of the melt (see page 13, lines 3 to 9, 17 to 24, and from line 29 to page 14, line 4).

Although the dispersion of the bubbles in the melt and their gradient of dispersion can be controlled to some

extent by the speed with which the tip is heated and then quenched, it is nevertheless difficult quantitatively to define the rate of porosity and the size of the bubbles. If the porosity is too large, the light transmission is lowered and most of the laser energy will be converted into heat. If the size of the bubbles is too large, the laser beam may be reflected in undesirable direction. According to the teaching of document D1, the conversion of a part of the energy into heat and a loss of a part of the laser energy by the undesirable reflection are avoided, i.e. the tip end face of the tapered portion only irradiates the laser energy and does not absorb it or a part of it, and converts it to heat energy (see page 4, lines 9 to 13; page 14, lines 7 to 33). Therefore, document D1 does not contain any pointer to the application of an additional coating to the tip end face of the known medical laser probe which would permit the conversion of a **predetermined percentage** of the laser energy into heat energy.

- 6.1.4 Document D2 describes the complete conversion of the laser energy into heat, which is applied to the tissue in contact with the heated element of the medical laser probe. The heat generating element being made of metal has such latent heat that if it had accidentally contacted tissue after the laser had fired but before it had cooled, it often perforated tissue, typically the wall of a blood vessel. As for the bubble melt of the medical laser probe according to document D1 which has a higher thermal inertia when compared to the infrared absorbing coating, the metal heat generating element according to document D2 has also a thermal inertia higher than the infrared absorbing coating and this requires the surgeon to exercise greater care than is necessary with a probe according to Claim 1.

6.1.5 Document D3 teaches the use of a coating of a diffusing medium at the probe to attain a better and homogeneous diffusion of the irradiated emerging light without excessive absorption (see page 2, lines 46 to 49 and lines 96 to 99). The intention - as in the teaching of document D1 - is essentially to use the laser energy for irradiating the tissue and not to submit it to an additional, controlled and sufficient heating of the probe in order to vaporise the tissue.

6.1.6 Therefore none of the above cited documents gives alone or in combination with one another any hint to the skilled person of providing the laser energy irradiation surface of a medical laser probe with a coating of infrared absorbing material which permits the simultaneous treatment of a patient's tissue by the radiation heat of the probe and the irradiation of the remaining energy of the laser beam.

6.2 Claim 9

6.2.1 Since Claim 9 is directed to a process involving roughening of the surface of the probe with a view to improving adherence of the coating of infrared absorbing material onto the radiation surface of the laser medical probe according to Claim 1 and since the state of the art does not disclose such a coating on the radiation surface of the probe, there is no hint in the state of the art leading the skilled person to the claimed process.

6.3 It follows from the above that it was not obvious to arrive at the claimed laser medical probe and at the related claimed method in view of the cited prior art. Therefore, the subject-matter of Claims 1 and 9 is considered to involve an inventive step set out in Articles 52(1) and 56 EPC.

6. Claims 1 and 9 being allowable, the same applies to the dependent Claims 2 to 8 and 10,11 respectively, whose patentability is supported by that of Claims 1 and 9, respectively.

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 in the following version:

Claims: 1 to 11 filed with letter of 26 March 1996,
Description: pages 1 to 5, 5a, 6, 6a, 7 to 12 filed with letter of 26 March 1996,
Drawings: sheets 1/4 to 4/4 (Figures 1 to 12) filed with letter of 29 July 1987.

The Registrar:



S. Fabiani

The Chairman:



H. Seidenschwarz