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D E C I S I O N
of 23 September 1994

Case Number: T 0954/91 - 3.2.2

Application Number: 86112166.3

Publication Number: 0217165

IPC: A61B 17/36

Language of the proceedings: EN

Title of invention:

Method of and apparatus for laser treatment of body lumens

Applicants:

Fox, Kenneth R. and
Coster, A. Arthur

Opponent:

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Headword:

-

Relevant legal norms:

EPC Art. 56, 84

Keyword:

"Inventive step - (yes) after amendment"
"Claims - functional features"

Decisions cited:

T 0068/85, T 0204/90

Catchword:

-



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D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 23 September 1994

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Decision under appeal:

Decision of the Examining Division of the European Patent Office dated 5 July 1991 refusing European patent application No. 86 112 166.3 pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: H. Seidenschwarz
Members: P. Dropmann
J. Van Moer

Summary of Facts and Submissions

- I. A notice of appeal was filed against the decision of the Examining Division refusing application No. 86 112 166.3 for lack of clarity (Article 84 EPC).
- II. During oral proceedings held on 23 September 1994, the Appellants filed a new set of Claims 1 to 5.
- III. The Appellants requested that the decision under appeal be set aside and a patent granted on the basis of Claims 1 to 5 filed at the oral proceedings and a description and drawings to be adapted.
- IV. Claims 1 to 5 read as follows:

"1. Apparatus for performing laser surgery in a body lumen (L) having an obstruction (X) therein, said apparatus comprising

- (a) a catheter (10, 110) for insertion into said body lumen (L), said catheter having a longitudinal axis (14, 114), proximal and distal ends, and a plurality of optical fibers (18a, 18b, 18c, 18d, 118), each with proximal and distal ends, said optical fibers (18a, 18b, 18c, 18d, 118) being disposed within said catheter (10, 110) and arranged in a predetermined array about said longitudinal axis (14, 114) for transmitting a laser beam from said proximal end to said distal end of the catheter (10, 110) to impinge on said obstruction (X);
and

- (b) a laser source (62) arranged adjacent the proximal end of said catheter (10, 110) for generating a non-continuous wave, pulsed laser beam (64) having a predetermined pulse duration, pulse repetition rate, and pulse energy;

characterized by

- (c) a multi-fiber optical scanner (16) arranged between said laser source (62) and said catheter (10, 110) for optically scanning the proximal ends of said optical fibers (18a, 18b, 18c, 18d; 118) with said pulsed laser beam (64) for sequentially directing said pulsed laser beam through preselected ones of said optical fibers (18a, 18b, 18c, 18d, 118) at different areas of said obstruction (X); and
- (d) the distal ends of some of said optical fibers (18a, 18b, 18c, 18d, 118) are converged radially inwardly or diverged radially outwardly at an angle toward or away from said longitudinal axis (14, 114).

2. Apparatus according to claim 1, whereby the non-continuous wave, pulsed laser beam (64) is an argon-ion laser beam having a pulse duration in the range of from 5 to 200 milliseconds, a pulse repetition rate from about 1 to 50 pulses per second and a pulse energy in the range from 150 to 500 millijoules.

3. Apparatus according to claim 2, whereby the laser beam (64) has a wavelength in the range of about 351 to 515 nanometres, and a spot size of 500 microns or less.

4. Apparatus according to any of claims 1 to 3, whereby the laser source (62) produces a laser beam (64) having a duty cycle selected to operate substantially at the threshold of the thermal relaxation time of the illuminated volume of the obstruction (X).

5. Apparatus according to claims 1 to 4, whereby the sequence of the scanning of the optical fibers (18a, 18b, 18c, 18d, 118) and the predetermined pulse duration, pulse repetition rate and pulse energy of said laser beam (64) being selected such that the pulsed

laser beam vaporizes the obstruction (X) with substantially no thermal necrosis of the surrounding tissue of the body lumen (L)."

Reasons for the Decision

1. The appeal is admissible.

2. *Amendments*

The claims meet the requirements of Article 123(2) EPC. Features (a) and (c) of Claim 1 have their basis in Claims 15 and 16 as originally filed, whilst feature (b) is supported by original Claim 15 in combination with page 26, second paragraph and page 12, first paragraph of the original description. Feature (d) is disclosed in original Claims 17 and 19.

As to dependent Claims 2 to 5, reference is made to original Claims 7, 2 and 6 and to page 27, line 24 to page 28, line 26 of the description as originally filed.

3. *Clarity*

The Board is satisfied that the claims are clear as prescribed by Article 84 EPC. According to the established case law of the Boards of Appeal (cf. T 68/85, OJ EPO 1987, 228 and T 204/90, dated 30 July 1991, unpublished) functional claim drafting (cf. Claims 1, 4 and 5) is permissible if:

- (i) the features cannot otherwise be defined more precisely without restricting the scope of the invention,

- (ii) the features provide instructions which are sufficiently clear for the expert to reduce them to practice without undue burden, if necessary with reasonable experiments, and
- (iii) the state of the art does not stand in the way of using such functional and therefore general and broad terminology.

4. *Novelty*

None of the documents mentioned in the second report and during the examining procedure discloses an apparatus having all the features specified in Claim 1. In particular, no apparatus for performing laser surgery in a body lumen is known from these documents which comprises, in combination, a catheter having a plurality of laser fibres, the distal ends of some of the fibres being converged inwardly or diverged outwardly at an angle toward or away from the longitudinal axis of the catheter, a laser source for generating a pulsed laser beam, and a multi-fibre optical scanner. The claimed apparatus is, therefore, novel over these documents within the meaning of Article 54 EPC.

5. *Inventive step*

- 5.1 As admitted by the Appellants, document EP-A-0 144 764 (D2) represents the state of the art which is closest to the subject-matter of Claim 1. This document discloses an apparatus for performing laser surgery in a body lumen (1) having an obstruction (2) therein. The apparatus comprises a catheter (3) for insertion into said body lumen, said catheter having a longitudinal axis, proximal and distal ends, and a plurality of optical fibres (5), each with proximal and distal ends, disposed within said catheter for transmitting a laser

beam from said proximal end to said distal end of the catheter to impinge on said obstruction (cf., in particular, Figure 1 and page 9, lines 5 and 6). The apparatus further comprises a laser source (4) arranged adjacent the proximal end of said catheter for generating a non-continuous wave, pulsed laser beam (cf. Figure 1, page 7, last line to page 8, second line and page 8, lines 18 to 20). Laser energy can be delivered in the visible wavelength range such as 500 nm through the optical fibres (cf. page 5, lines 18 to 24 and page 8, lines 25 to 28). In addition, it is stated in document D2, page 9, lines 7 to 10 that steering means can be included at the tip of the catheter "of a type currently used in gastrointestinal fiberoptic endoscopy" and "focusing means at the tip which would provide radiation over a well-delineated area or linear region of atheromatous plaque".

5.2 Starting from the disclosure of document D2, the technical problem underlying the present invention can be seen, in accordance with the statements in the paragraph bridging pages 12 and 13 and at page 27, second paragraph of the application, as providing an apparatus which allows:

- (i) complete coverage of the cross-sectional area of the body lumen confronting the distal end of the catheter with the laser beam, and
- (ii) aiming of the laser beam to minimise the risk of perforation of the luminal wall, or, alternatively,
- (iii) achieving overlapping of laser impingement or aiming at areas not impinged by the laser beam or blind spots caused by the positioning of other elements in the catheter.

5.3 Partial problems (i) and (ii) are solved by arranging a multi-fibre optical scanner (feature (c) of Claim 1) between the laser source and the catheter of the apparatus known from document D2 and by providing some of the optical fibres with distal ends which are converged radially inwardly at an angle toward the longitudinal axis of the catheter (first alternative of feature (d) of Claim 1). Partial problems (i) and (iii) are solved also by arranging a multi-fibre optical scanner (feature (c) of Claim 1) and by providing some of the optical fibres with distal ends which are diverged radially outwardly at an angle away from said longitudinal axis (second alternative of feature (d) of Claim 1).

5.4 In the Board's judgment, no inventive step can be seen in feature (c), i.e. adding a multi-fibre optical scanner to the apparatus known from document D2. Indeed, the fact that it is known from document D1 (i.e. the article "Multispot laser photocoagulation system using a fiber bundle scanner" by H. Fujii et al., Applied Optics, Vol.21, No.19, 1 October 1982, pages 3437 to 3442) to cover an increased area of the skin to be laser-treated by equipping a photo-coagulation system with a fibre bundle scanner (cf. document D1, in particular Figure 2), renders it obvious to use a similar scanner in the apparatus known from document D2 in order to solve a similar problem, namely partial problem (i).

5.5 However, the Board is convinced that, in the light of the state of the art as known from the documents cited in the search report and during the examination procedure, it is not obvious to solve partial problems (ii) or (iii) by feature (d), i.e. providing some of the optical fibres with distal ends which are converged radially inwardly or diverged radially outwardly at an

angle toward or away from the longitudinal axis of the catheter.

Amongst these documents, documents D2 and US-A-3 858 577 are the only ones which deal with aiming of the laser beams at the distal end of the catheter. As mentioned at the end of point 5.1 above, steering means of a type currently used in gastrointestinal fibreoptic endoscopy can be included at the tip of the catheter known from document D2, page 9, lines 7 and 8. Such steering means, however, do not include means for converging or diverging the ends of the laser fibres relative to the catheter axis, as pointed out by the Appellants during the oral proceedings. The statement at page 9, lines 7 and 8 of document D2, therefore, cannot have suggested feature (d) of Claim 1. Neither can the statement at page 9, lines 8 to 10 that focusing means can be included at the top of the catheter have given a hint to feature (d), since focusing means solve the problem of aiming by using optical means rather than by skewing the distal ends of the laser fibres relative to the catheter axis.

Document US-A-3 858 577 cited in the search report relates to a flexible endoscope with a surgical laser connected thereto for simultaneous viewing and performance of surgery on the interior stomach wall. According to Figure 4 and column 4, lines 31 to 34 of this document, the distal end of the laser fibre is provided with a bend. This bend is required by the fact that the laser fibre (30) is carried on the side of the endoscope (15) and that, therefore, bending of the fibre is necessary in order to converge the lines of sight of the endoscope and the laser fibre. Thus, the embodiment illustrated in Figure 8, in which embodiment the fibre is positioned within the endoscope, does not include a fibre having a bend. It follows that the problem

underlying the US document is different from problem (ii) and (iii) underlying the claimed apparatus, in which the laser fibres are disposed within the catheter. Hence, the skilled person could not have received any clue from this document to solve the problem of the invention in the way indicated in Claim 1.

5.6 The apparatus according to Claim 1 thus cannot be derived in an obvious manner from the state of the art cited in the search report and during the examining procedure and, therefore, involves an inventive step in accordance with Article 56 EPC.

6. The subject-matter of Claim 1 is, therefore, patentable having regard to Articles 52(1), 54 and 56 EPC.

Dependant Claims 2 to 5 define particular embodiments and meet likewise the requirements of the EPC.

7. During the oral proceedings, the Appellants' attention was drawn to the fact that the embodiment illustrated in Figures 1 to 4 did not fall within the scope of Claim 1, because this embodiment did not comprise optical fibres whose distal ends were converged radially inwardly or diverged radially outwardly at an angle toward or away from the longitudinal axis of the catheter. Inflation of elongate balloon 22, which extends parallel to the axis of the laser fibre bundle 16, leads to shifting of the laser fibre bundle radially toward the axis 14 of the catheter 10 (cf. page 15, lines 14 to 20, page 16, lines 1 to 10, and page 18, lines 18 to 27 of the description) rather than to skewing or converging of the distal ends of the fibres relative to the longitudinal catheter axis. Figures 1 to 4, the corresponding text of the description and the reference numerals of the claims

relating to the embodiment according to these figures are therefore to be deleted when making the description and the drawings consistent with the claims.

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 with Claims 1 to 5 as filed during the oral proceedings and a description and drawings to be adapted.

The Registrar:



S. Fabiani

The Chairman:


H. Seidenschwarz