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DECISION of 14 February 2006

Case Number: T 1132/03 - 3.2.02

Application Number: 94924377.8

Publication Number: 0720449

IPC: A61B 17/39

Language of the proceedings: EN

Title of invention:

ELECTROSURGICAL APPARATUS

Patentee:

American Medical Systems, Inc.

Opponent:

Ms. Chiyoko Horiuchi

Headword:

Relevant legal provisions:

EPC Art. 54, 56

Keyword:

"Novelty (no - main request)"

"Inventive step (no - auxiliary requests)"

Decisions cited:

Catchword:



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Boards of Appeal

Chambres de recours

Case Number: T 1132/03 - 3.2.02

DECISION

of the Technical Board of Appeal 3.2.02 of 14 February 2006

Appellant: American Medical Systems, Inc.

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Representative: Vossius & Partner

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Respondent: Ms. Chiyoko Horiuchi

(Opponent) Isobe 3-36-14

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Decision under appeal: Interlocutory decision of the Opposition

Division of the European Patent Office posted 16 July 2003 concerning maintenance of the European patent No. 0720449 in amended form.

Composition of the Board:

Chairman: T. Kriner Members: M. Noël

A. Pignatelli

Summary of Facts and Submissions

I. By interlocutory decision dated 16 July 2003, the opposition division decided to maintain the European patent No. 0 720 449 in an amended form, having regard, in particular, to the prior art documents:

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E3: DE-A-3 626 371, and

E5: US-A-3 910 279.

II. The appellant (patentee) lodged an appeal against this decision received at the EPO on 19 September 2003 and paid the appeal fee on the same date.

A statement setting out the grounds of appeal was filed on 25 November 2003, along with amended claims according to a main and several auxiliary requests.

III. Oral proceedings were held on 14 February 2006. At the end of the oral proceedings the requests of the parties were as follows:

The appellant requested that the decision under appeal be set aside and the patent be maintained as granted (main request) or on the basis of claims 1 to 11 according to the first auxiliary request, or claims 1 to 10 according to the second auxiliary request, or claims 1 to 10 of the third auxiliary request, or claims 1 to 10 of the fourth auxiliary request, or claims 1 to 10 of the fifth auxiliary request, all filed with letter dated 25 November 2003.

The respondent (opponent) requested that the appeal be dismissed.

IV. Claim 1 according to the different requests reads as follows:

Main request

"An apparatus for electrosurgical incision of a stricture within or adjacent to a body lumen, which apparatus includes an introducer means (6) which is elongated and has a distal end, a proximal end (7) and a longitudinal axis defined as extending from the proximal end to the distal end of the introducer means, an electrically conducting, deflectable wire (1) associated with the introducer means for introducing the wire into the body lumen, means for deflecting a proximal portion of the wire outwardly relative to the introducer means, a source of RF electric current connected to the wire and means for transmitting RF electric current through the wire when it is in the deflected position, characterized in that the means for deflecting is capable of deflecting the wire to form a loop outwardly in a direction transverse to and to the side of the longitudinal axis of the introducer means."

First to third auxiliary requests

"An apparatus for electrosurgical incision of a stricture within or adjacent to a body lumen, comprising

an introducer means (6) which is elongated and has a distal end, a proximal end (7) and a longitudinal

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axis defined as extending from the proximal end (7) to the distal end of the introducer means (6),

an electrically conducting, deflectable wire (1) associated with the introducer means (6) for introducing the wire (1) into the body lumen,

means for deflecting a proximal portion of the wire outwardly relative to the introducer means,

a source of RF electric current connected to the wire (1) and

means for transmitting RF electric current through the wire (1) when it is in the deflected position, characterized in that

the wire (1) defines a loop (2) at the proximal end (7) of the apparatus, and two distal ends (3, 4) extending towards the distal end of the apparatus, and

the means for deflecting is capable of deflecting the wire (1) to form a loop outwardly in a direction transverse to and to the side of the longitudinal axis of the introducer means (6) by motion of one distal end (4) of the wire (1) relative to the other distal end (3) of the wire."

Fourth and fifth auxiliary requests

the content of claim 1 to the previous auxiliary requests and the following feature added at the end of the claim:

"and the portion of wire deflected outwardly is in the form of a loop defining a monopolar electrosurgical knife."

V. Arguments of the parties

(i) At the oral proceedings the appellant submitted that the subject-matter of claim 1 according to the main request differed from the cited prior art by the use of radio-frequency (RF) electrical energy for supplying the deflected wire instead of high-frequency (HF) current as in documents E5 and E3. The use of electrical current in the narrower range of RF provided technical advantages such as more precise and less traumatic cutting operation. As a consequence, the claimed subject-matter was novel over the prior art.

Claim 1 according to the first to fifth auxiliary requests specified that the wire loop was formed by relative motion of two distal ends of the wire extending towards the distal end of the apparatus. With respect to document E5 which disclosed a transverse loop formed by simply pushing on the distal end of the wire, the present invention enabled transverse loops having various configurations and sizes to be formed and controlled more easily. Moreover, buckling of the wire was avoided by the fact that, unlike E5, the deflecting mechanism of the present patent did not require one distal end of the wire to be pushed while the other end remained fixed.

E3 disclosed the relative motion of two wires extending towards the distal end of the apparatus, but the loop so formed projected axially from the proximal end outwards and not transversally to the side of the longitudinal axis of the introducer

means. Moreover, the snare assembly disclosed in E3 was used for clamping and cutting polyps and, therefore, was not suitable for electrosurgical incision of a stricture. Due to essential differences of design and application between the apparatus of E3 and E5, the skilled person would not have thought of combining the teachings of these two documents to arrive at the claimed subject-matter.

Claim 1 according to the fourth and fifth auxiliary requests specified further that the loop formed as above was part of a monopolar electrosurgical knife. Since this additional feature was not disclosed by either of the cited documents, the claimed subject-matter was also novel and inventive over the prior art.

(ii) The respondent (opponent) submitted that the HF used in documents E5 and E3 was part of the wider range of RF and, therefore, deprived the subjectmatter of claim 1 of the main request from novelty.

As to the auxiliary requests, the skilled person was prompted to combine the teaching of document E5 which disclosed the formation of a transverse, variable loop by pushing the distal end of the wire, with the teaching of document E3 which disclosed the relative motion of two distal ends of the same wire. Moreover, since, E3 was related to a neighbouring medical field and disclosed an apparatus for resecting or cutting a body tissue, and since the large loop formed at

the axial end of the apparatus projected also transversally with respect to the longitudinal axis of the apparatus, the above combination was clearly suggested. Therefore, none of the auxiliary requests met the requirement of inventive step.

Reasons for the Decision

- 1. The appeal is admissible.
- 2. Main request

Document E5 discloses (see Figures 1 to 6) an apparatus for electrosurgical incision of a stricture within or adjacent to a body lumen, including an elongated introducer means 1 having a distal end, a proximal end and a longitudinal axis extending from the proximal to the distal ends. The apparatus further includes an electrically conducting, deflectable wire 4 associated with the introducer means for introducing the wire into the body lumen, means for deflecting a proximal portion of the wire outwardly relative to the introducer means and a source of electric current connected to the wire (connector 12) for transmitting electric current through the wire when it is in the deflected position (see column 4, lines 31 to 43). Moreover, in operation, the wire is deflected to form a loop outwardly in a direction transverse to and to the side of the longitudinal axis of the introducer means, as shown in Figures 1 and 5.

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According to document E5 the wire is supplied with high-frequency (HF) electrical current, while according to the present claim 1 the wire is supplied with radio-frequency (RF) current. However, it is general knowledge that high frequencies (HF) extend over the range from about 3 MHz to 30 MHz and form part of the much wider range of radio frequencies (RF) which extend from 3 Hz to 300 GHz. Therefore the general and undefinite use of RF is disclosed by the specific use of HF according to document E5, the more since the patent specification does not mention any particular frequency range or value, and the appellant has not brought any evidence as support of its arguments.

Consequently, the subject-matter of claim 1 according to the main request is not novel vis-à-vis document E5 (Article 54 EPC).

- 3. First to fifth auxiliary requests
- 3.1 Apart from minor modifications in the preamble ("comprising"; reference signs), claim 1 according to first to third auxiliary requests differs from the main request principally by the following two additional features:
 - "the wire (1) defines a loop (2) at the proximal end (7) of the apparatus, and two distal ends (3, 4) extending towards the distal end of the apparatus, and"
 - (the transverse loop is formed) "by motion of one distal end (4) of the wire (1) relative to the other distal end (3) of the wire."

As shown in Figures 1 and 5 of E5, the distal end 4 of the wire is free to move inside the introducing tube 1 and the proximal end 5 of the wire is fixed to the corresponding end of the tube. Thus, when the free distal end of the wire is pushed towards the fixed proximal end of the same, the wire defines a loop at the proximal end of the apparatus by motion of the distal end of the wire relative to the other (fixed) end of the wire.

Therefore, the claimed subject-matter differs from the disclosure of E5 only by the design according to which, the wire does not end at the proximal end of the introducer means, but returns to the distal end of the apparatus so as to provide a second distal end instead of only one as shown in document E5.

- 3.2 The technical problem referred to in the present patent (see paragraphs 16 and 52) of providing an apparatus for electrosurgical incision well adapted for trasurethral incision of the prostrate (TUIP) or of a ureteral stricture, is generally known and already resolved by the apparatus according to E5 (see column 1, lines 4 to 6). Therefore, the objective technical problem underlying the above-mentioned distinguishing features of claim 1 is restricted to provide an alternative solution for controlling the deflection of the wire loop and thereby changing the configuration of the cutting assembly.
- 3.3 Document E3 (Figure 1) relates to a snare assembly for endoscope, more specifically for clamping and cutting a polyp within a living body by means of a loop of snare

or wire 20 comprising two distal ends which extend each towards the distal end of the apparatus. In order to vary the size of the snare loop by relative motion of the two distal ends of the wire, these later are connected to an operation rod 40 and a slide member 34 (via a stopper 22), respectively (see column 6, lines 50 to 57 and from column 6, line 67 to column 7, line 10). Therefore, the claimed alternative solution of providing two distal ends for the wire was directly suggested to the skilled person by the disclosure of E3 which, moreover, belongs to a similar technical field or at least very close to that of E5 or the present patent.

The arguments set forth by the appellant at the oral proceedings (see point V(i) above) failed to convince the Board because the alleged advantages of the invention over the prior art have no basis in the patent specification. The skilled person who starts from document E5 as closest prior art and who is looking for alternative means for adjusting the configuration and size of the loop will immediately find in E3 a suitable solution. The other differences exhibited by E3 are irrelevant for the assessment of the inventive step.

3.4 Claim 1 according to the fourth and fifth auxiliary requests differs from the previous auxiliary requests by the additional feature according to which "the portion of wire deflected outwardly is in the form of a loop defining a monopolar electrosurgical knife".

As already observed in above point 2, document E5 discloses an electrosurgical instrument for resecting

the tissue of a body cavity (see column 1, lines 4 to 6), the portion of wire deflected outwardly forming the resecting section and being electrically connected to a source of HF current.

Following the definition of the term "monopolar" given in the present patent (paragraph 33), the deflectable wire of the E5 apparatus is also electrically connected at its distal end (Figure 3). This end, therefore, acts as the active electrode while the current is returned through the patient body via the introducer tube. The monopolar type of the electrosurgical knife is thus also known from document E5 and does not confer an inventive step to the subject-matter of claim 1.

3.5 It results therefrom that the subject-matter of claim 1 according to any of the first to fifth auxiliary requests does not meet the requirement of inventive step within the meaning of Article 56 EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

V. Commare T. Kriner

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