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Datasheet for the decision of 29 June 2010

Case Number: T 1138/09 - 3.2.02

Application Number: 92916254.3

Publication Number: 0595967

IPC: A61B 17/36

Language of the proceedings: EN

Title of invention:
Surgical coagulation device

Patentee:
CANADY, Jerome

Opponents:
01 Erbe Elektromedizin GmbH
02 KeyMed (Medical & Industrial Equipment) Limited
03 ERBE Medical UK Limited

Headword:
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Relevant legal provisions:
EPC Art. 54(1)(2), 53(c), 56
EPC R. 103(1)(a)

Relevant legal provisions (EPC 1973):
-

Keyword:
"Novelty (yes)"
"Inventive step (yes)"
"Reimbursement of appeal fees (no)"

Decisions cited:
T 0712/93, T 0641/00, G 0002/88, G 0002/08

Catchword:
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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 1138/09 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 29 June 2010

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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted 10 March 2009 rejecting the opposition filed against European patent No. 0595967 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman: M. Noël
Members: C. Körber
A. Pignatelli

Summary of Facts and Submissions

I. By its decision posted on 10 March 2009 the Opposition Division decided to reject the oppositions of opponents O1, O2 and O3 against European Patent No. 0 595 967.

II. Appeals were lodged against this decision by the appellants (opponents O1 and O3) in notices received on 20 May 2009. The appeal fees were paid on the same day. The statements setting out the grounds of appeal were received on 17 July 2009.

III. In a communication of 15 February 2010, the Board forwarded its provisional opinion to the parties.

IV. Oral proceedings were held on 29 June 2010, at the end of which the parties' requests were as follows:

The appellants requested that the decision under appeal be set aside and that the European patent be revoked. They further requested reimbursement of the appeal fees.

The respondent (patentee) requested that the appeals be dismissed.

Opponent O2 did not file any submissions and was not present at the oral proceedings, as previously announced.

V. The following documents are of importance for the present decision:

D1: US-A-4 060 088

With respect to "prior use B" (PUB), the following pieces of evidence were submitted:

PUB1 - Affidavit from H. Reich dated 29 December 2000
PUB2 - Letter from H. Reich to B. G. Rigby dated 10 October 1990 (Exhibit A)
PUB3 - Clinical Report by H. Reich (Exhibit B)
PUB4 - Brochure "The Beamer Two Argon Beam Coagulation Unit" by Beacon Laboratories, Inc., dated 1991
PUB5 - Brochure "Beacon Laboratories Products for Laparoscopic Surgery" by Beacon Laboratories, Inc., dated 1991
PUB6 - Brochure "Orientation to Laparoscopy" by Beacon Laboratories, Inc. (4 pages)
PUB7 - Printout of FDA database search result "510 (k) Premarket-Notification Database" dated 20 June 2005
PUB8 - Memorandum from E.C. Whitehead to J. Young, R. Fleenor and W. Goslau dated 9 April 1991
PUB9 - Memorandum from J. Young, D. Fleenor and B. Goslau to E.C. Whitehead dated 3 May 1991
PUB10 - Course materials for training courses "Advanced Operative Laparoscopy for General Surgery" scheduled for March, April and May 1991 by The Advanced Laparoscopy Training Center, Marietta, Georgia
PUB11 - DVD with video film and colour photographs (pictures 1 to 34) reproduced therefrom
PUB12 - Affidavit from W.F. Goslau dated 12 April 2006.

VI. Claim 1 of the patent as granted reads:

"A surgical tissue coagulator (A) comprising an elongate, biocompatible, tube (10) having an open distal end (12) and a proximal end (14);
means (22) for connecting the proximal end (14) of said tube (10) with a source (24) of an inert, ionizable gas so that a stream of said gas can flow through said tube (10) and exit the distal end (12) of said tube (10);
a handle 18 attached to said tube (10) adjacent the proximal end (14) of the tube (10) for maneuvering said tube (10);
a wire (28) within said tube (10) for conducting radiofrequency current, the wire (28) having a distal end (30) for positioning adjacent the distal end (12) of said tube (10), and means (32) at the distal end (30) of said wire (28) for discharging an arc (34) of radiofrequency energy away from the distal end (30) of said wire (28) within said stream of inert gas exiting the distal end (12) of said tube (10) so as to form an ionized gas stream which is capable of coagulating tissue (38) during endoscopic surgery within a patient, the wire (28) having a proximal end (40) opposite the distal end (30) of the wire (28), and means (42) for connecting the proximal end (40) of the wire (28) with a source (44) of radiofrequency energy,
characterized in that said tube (10) and said wire (28) are flexible, the tube has further an external diameter of less than about 5 mm, is insertable into a surgical endoscope (16) having a length of at least about 35 cm, and in that said handle is adapted for maneuvering said tube (10) within said endoscope (16) while said handle (18) is outside said endoscope (16)."

VII. The arguments of the appellants can be summarised as follows:

Prior use PUB related to a single subject comprising all features of claim 1. The presence of a wire within the tube of the coagulator as defined in the preamble was explicitly mentioned in affidavits PUB1 and PUB12. The only features of claim 1 not explicitly mentioned in PUB12 were K1, K2 and K6 (see feature breakdown presented below in point 2 of the reasons). However, PUB12 referred to the video film PUB11, with picture 7 thereof clearly disclosing the flexibility of the tube (K1). Since the wire was within the tube, as stated in PUB12, its flexibility was disclosed implicitly (K2). With regard to the endoscope referred to in features K4 to K6, it was to be noted that claim 1 was not directed to a combination of a coagulator and an endoscope, but merely required the claimed coagulator to be suitable for insertion into a surgical endoscope. A laparoscope was a specific type of endoscope, which also became clear from claim 13 of the contested patent, and normally comprised a working channel. Moreover, the trocar shown in the video film PUB11 could be regarded as an external working channel of the laparoscope. Since PUB12 stated that the probe was moved within the catheter introduced into the patient, it was a necessary consequence that the handle was outside the endoscope while the tube was being manoeuvred, as defined in feature K6. This was also visible in the video film PUB11 (pictures 6 and 33) and clear from the fact that the handle was thicker than the tube (picture 7). Accordingly, PUB anticipated all features of claim 1.

The claimed subject-matter was obvious either from D1 alone, taking account of the general knowledge of the skilled person, or from D1 in combination with prior use PUB. The problem to be solved was to adapt the coagulator disclosed in D1 for conventional open surgery so that it could be used with a flexible endoscope, the latter in general comprising a working channel. This obvious adaptation would necessarily lead the skilled person to the characterising features K1 to K6, of which K5 and K6 were to be regarded as trivial. Furthermore, PUB gave a clear indication that tissue coagulators could be used in endoscopic surgery, and that a coagulator comprising features K1 to K6 was indeed available to the public before the priority date. The fact that video film PUB11 related to multi-port surgery, whereas the invention was presented as having the alleged advantage of allowing single-port surgery, was concerned with a method of using the device, which was excluded from patentability and could thus not be taken into account for assessing inventive step.

The appeal fees should be reimbursed due to a number of substantial procedural violations by the Opposition Division. In particular, the right to be heard was violated because the impugned decision stated for the first time that it was not clear whether PUB5 and PUB11 actually related to the same device, because the reasoning of the decision was based on the assumption that a laparoscope did not comprise a working channel, and because the appellants had no opportunity to comment on these allegations. Furthermore, the Opposition Division had failed to evaluate PUB1 as

evidence with respect to the presence of a wire in the tube.

VIII. The arguments of the respondent can be summarised as follows:

Prior use PUB related to a number of different coagulators none of which comprised in combination all the features of claim 1. Its subject-matter was therefore novel.

The problem to be solved with respect to D1 as formulated by the appellants was not correct as it comprised elements of the solution according to the claimed invention. The objective problem was rather to provide a coagulator usable for endoscopic surgery with any suitable endoscope, as indicated in lines 4 to 10 of column 3 of the patent specification. The fact that the tube was insertable into a surgical endoscope, as defined in features K4 to K6 of the characterising portion of claim 1, permitted single-port endoscopic surgery with direct observation of the treatment site through the endoscope, which could thus remain in its position. This procedure was less invasive than the multi-port technique disclosed in PUB where the coagulator was inserted through a trocar and the treatment site observed through a separately inserted rigid laparoscope.

Reasons for the Decision

1. The appeal is admissible.

2. The following feature breakdown of the characterising features of claim 1 in suit, proposed by opponent O3 in a letter of 20 June 2005, is used by the Board for the present decision:

K1: said tube (10) is flexible,
K2: said wire (28) is flexible,
K3: the tube has further an external diameter of less than about 5 mm,
K4: the tube is insertable into a surgical endoscope (16) having a length of at least about 35 cm,
K5: said handle is adapted for maneuvering said tube (10) within said endoscope (16),
K6: while said handle (18) is outside said endoscope (16).

3. Novelty

With respect to "prior use B" (PUB), the appellants have submitted several pieces of evidence (PUB1 to PUB12) relating to a number of devices used under various circumstances. The relevant issue for assessing novelty is whether one of the allegedly used devices, each taken separately, actually comprised all the features of claim 1 in combination.

Affidavit PUB12 refers to a probe for laparoscopic operations connected to an apparatus denoted as "Beamer Two". As conceded by the appellants, features K1, K2 and K6 of claim 1 are not explicitly mentioned in this document. Moreover, PUB12 is also silent with respect to the use of a surgical endoscope as referred to in features K4 and K5. In the paragraph bridging pages 3 and 4, it is merely stated that the probe was moved

within a catheter, and in the last paragraph on page 4, that the diameter of the tube was adapted for a catheter for laparoscopic operations. From these statements it cannot be clearly derived, however, that the handle mentioned in PUB12 is adapted for manoeuvring the tube within an endoscope, as required by feature K5. Accordingly, the device described in PUB12 alone fails to disclose features K1, K2, K5 and K6.

Affidavit PUB12 (page 2, second paragraph) further refers to the video film identified as PUB11. This film comprises two tapes (tape 1 and tape 2) showing a number of laparoscopic surgical operations using various devices, with oral presentations and explanations given by the surgeons involved. Tape 1 at the beginning refers orally to a device called "the argon coagulator" and then to "the beamer" (picture 12 and onwards) with a 5 mm tip for insertion into cannulas used in multi-port laparoscopic surgery. Tape 2 shows various laser cutting and coagulation procedures (pictures 16 to 30), unrelated to an RF inert gas coagulator as claimed; thereafter, it comprises a (partially repetitious) presentation of the explanations given by one of the surgeons on tape 1, picture 3 et seq.; in the second part, it finally refers to "Beamer One" and "Beamer Two" (picture 31 and onwards) for multi-port laparoscopic surgery. Consequently, the sequences shown in video film PUB11 do not relate to a single device, contrary to the appellants' assertions. This is also evident from the structural differences in the geometrical shape of the coagulators shown, for instance, in pictures 5, 7, 13 and 33.

Picture 7, on which the appellants primarily relied with respect to feature K1, shows a device labelled as "Flexible Argon Beam Probe". In the subsequent picture 8, reference is made to the "Lap Beam$_{TM}$". In the soundtrack underlying pictures 7 and 8, it is stated that "Beacon have introduced a flexible argon beam probe which can be introduced through a 5 mm surgiport". A wire within the tube and a handle attached at the proximal end of the tube is neither visible nor mentioned. In the Board's view, it is not clear that the flexible probe shown in picture 7 actually corresponds to the probe connected to "Beamer Two" mentioned in affidavit PUB12 (page 3, penultimate paragraph).

The probe connected to "Beamer Two" as shown in tape 2 (pictures 31 to 33) is evidently rigid. It comprises a handle and is insertable through a trocar in multi-port laparoscopic surgery, while laparoscopic observation of the operation site is performed through a separate port. In the Board's view, said trocar cannot be regarded as an external working channel of the laparoscope (which is a rigid endoscope), contrary to the assertions of the appellants.

A probe comprising a **flexible** tube with a **flexible** wire therein and a handle adapted for manoeuvring the tube **within an endoscope**, while the handle is outside the endoscope, is neither shown nor explained anywhere else in video film PUB11.

In their written submissions, the appellants explicitly referred to affidavit PUB1 (page 2, lines 9 and 10)

with respect to the presence of a flexible wire within a tube. This document does not mention, however, that the tube is flexible as well. Moreover, it is entirely silent with respect to a handle and does not comprise any information regarding the length of the tube. Furthermore, the coagulator described therein is connected to the "Beamer One", i.e. a device different from the "Beamer Two" referred to in PUB12. Affidavit PUB1 does not refer to any video film. PUB2 and PUB3 cited in PUB1 do not reveal any further relevant information.

Brochure PUB5 refers to various "disposable electrodes" that can be connected to the coagulation units "Beamer One" or "Beamer Two". It is stated that these electrodes can be used with a 5 mm trocar, but there is no mention at all of an endoscope. Reference is also made in PUB5 to a "Free video on Beacon products", but it remains unclear whether this video corresponds to the video film PUB11 referred to in PUB12. In any case, PUB5 fails to disclose a wire, and even less so a flexible one, and gives no indication that the "electrodes" or tubes are flexible. Furthermore, this brochure is silent with respect to the presence of an endoscope as referred to in features K4 to K6.

Brochure PUB6 also refers to the coagulation units "Beamer One" and "Beamer Two" and additionally describes the connection of the "laparoscopic electrode" to a "pencil". However, its relevant technical content does not go beyond that of PUB5.

PUB4 and PUB7 to PUB10 are of no further relevance.

It follows that none of the various devices referred to in PUB1 to PUB12 reveals directly and unambiguously the combination of features as claimed. Accordingly, the subject-matter of claim 1 is new vis-à-vis "prior use B" within the meaning of Article 54(1) and (2) EPC.

4. Inventive step

4.1 The subject-matter of claim 1 is distinguished vis-à-vis the disclosure in document D1, representing the closest prior art, by the features of the characterising portion, i.e. K1 to K6. This is undisputed by all parties. In view of the filing date of D1 (1976), it is evident that the surgical tissue coagulator described therein was designed for use in conventional open surgery, as was also accepted by the parties. This implies inter alia that the tube 18 described in D1 must be rigid, since a flexible tube would not allow the surgeon to manipulate the coagulator precisely towards the tissue site to be treated.

4.2 The objective problem to be solved by the features of the characterising portion of claim 1 is to provide a coagulator that can be used with any suitable endoscope, either rigid or flexible, thereby increasing the instrument's range of surgical applications, while at the same time reducing the degree of invasiveness. This problem is derivable from column 1, lines 52 to 58, and column 3, lines 4 to 10. Even though the technical problem should not be formulated to contain pointers to the solution or partially to anticipate it, the mere fact that some feature also appears in a claim (in this case, the endoscope mentioned in features K4 to K6)

does not automatically exclude it from appearing in the formulation of the problem (see T 641/00, headnote).

4.3 In the Board's judgment, the inventive step of the claimed solution resides in the combination of all features of the claim, i.e. the structural features of the coagulator (K1 to K3) and the fact that the coagulator is specifically designed for insertion into an endoscope as defined by features K4 to K6, which are functional features. The coagulator according to the invention involves an inventive step since the claimed solution permits the coagulator to be used in single-port endoscopic surgery with direct and continuous observation of the treatment site. The operation can be performed and observed through a single endoscope which may be flexible and can remain in the desired position to which it was previously manoeuvred.

Contrary to the assertions of the appellants, Article 53(c) EPC is not relevant in the present case since the claim is directed to a coagulator, i.e. a physical entity, and not to a method of treatment by surgery or therapy, i.e. a physical activity, which represents a different category of claim (G 2/88, point 2.2 of the reasons). In general, a claim to a physical entity confers absolute protection, which also encompasses all its uses (G 2/88, point 5 of the reasons).
Article 53(c) EPC, second sentence, explicitly states that the exclusion provision does not apply to products for use in such methods. Whereas method claims are absolutely forbidden in order to leave the physician free to act unfettered, product claims are allowable provided their subject-matter is new and inventive (G 2/08, point 5.7 of the reasons). The fact that some

features of the claimed apparatus are functional, as in the present case, does not in itself transform the claim into a method claim (T 712/93, point 3 of the reasons). There is no reason to disregard advantages achieved in the use of the claimed coagulator when assessing inventive step, even when this use relates to surgery or therapy.

4.4 Document D1 gives no hint in the direction of the above-mentioned problem and its solution. In fact its teaching points away from them since making use of a flexible tube instead of a rigid one would prevent the coagulator from being used in open surgery as indicated above (point 4.1). The appellants' argument that adapting the coagulator disclosed in D1 for use in a flexible endoscope would necessarily lead the skilled person to the subject-matter of claim 1 in view of his general technical knowledge is therefore based on hindsight.

4.5 As clearly shown in video film PUB11 (see the sequence comprising picture 33 on tape 2), an operation technique is presented where the coagulator is not inserted through the laparoscope, but through a separate trocar instead. This requires multi-port surgery, associated with a higher degree of invasiveness and less visual control of the treatment process than the single-port technique permitted by the coagulator of the invention. Moreover, the trocar must be manoeuvred separately towards the site of treatment under endoscopic observation. Although it is usual for a laparoscope to be provided with a working channel, there is no suggestion in the video film that the separate trocar should be done away with entirely or

that the coagulator should acually be inserted through such a working channel in the laparascope, if one were present. Even additionally taking into account the teaching of picture 7 showing a flexible tube, there is no such hint since the soundtrack of the corresponding sequence of the video film clearly states that "Beacon have introduced a flexible argon beam probe which can be introduced through a 5 mm surgiport", i.e. through a separate trocar. Moreover, a trocar is usually straight and rigid. It thus remains unclear what purpose the flexibility of the tube to be inserted through the trocar is to serve. A flexible endoscope is neither shown nor mentioned in video film PUB11.

Insertion of a coagulator into a separate trocar is also described in PUB5 (page 1, bottom of left-hand column) and PUB6 (page 1, 2nd paragraph). In PUB12 (page 4) the term "catheter" is used instead of "trocar", but the teaching is similar in that the catheter and the laparoscope are separate entities, and there is no suggestion that the coagulator is to be introduced directly into the laparoscope. Accordingly, even when combining the teachings of D1 and PUB in the manner suggested by the appellants, the skilled person would not arrive at a coagulator specifically designed for insertion into a suitable endoscope, as defined by the functional features K4 to K6 in claim 1.

4.6 It follows that the subject-matter of claim 1 is not obvious on the basis of either document D1 alone in view of the general knowledge of the skilled person, or in the light of D1 in combination with PUB. Therefore the subject-matter of claim 1 involves an inventive step within the meaning of Article 56 EPC.

5. Reimbursement of the appeal fee

The appellants' requests for reimbursement of the appeal fees are to be refused under Rule 103(1)(a) EPC since a precondition for reimbursement is that the appeal must be allowable, i.e. it must be successful, which is not the case here.

Order

For these reasons it is decided that:

1. The appeals are dismissed.

2. The requests for reimbursement of the appeal fees are refused.

The Registrar: The Chairman:

D. Sauter M. Noël