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**Datasheet for the decision
of 10 August 2011**

Case Number: T 1651/08 - 3.2.02

Application Number: 99970908.2

Publication Number: 1123058

IPC: A61B 18/14

Language of the proceedings: EN

Title of invention:

Open vessel sealing forceps with stop member

Patentee:

Covidien AG

Opponent:

KLS Martin GmbH + Co. KG

Headword:

-

Relevant legal provisions:

EPC Art. 123(2), 56

Relevant legal provisions (EPC 1973):

-

Keyword:

"Extended subject-matter (no) "

"Inventive step (yes) "

Decisions cited:

-

Catchword:

-



Case Number: T 1651/08 - 3.2.02

DECISION
of the Technical Board of Appeal 3.2.02
of 10 August 2011

Appellant:
(Opponent)

KLS Martin GmbH + Co. KG
Am Gansacker 1b
D-79224 Umkirch (DE)

Representative:

Maucher, Wolfgang
Patent- und Rechtsanwaltssozietät
Maucher, Börjes & Kollegen
Urachstrasse 23
D-79102 Freiburg im Breisgau (DE)

Respondent:
(Patent Proprietor)

Covidien AG
Victor von Bruns-Strasse 19
CH-8212 Neuhausen am Rheinfall (CH)

Representative:

Marsh, Roy David
HOFFMANN EITLE
Patent- und Rechtsanwälte
Arabellastraße 4
D-81925 München (DE)

Decision under appeal:

**Decision of the Opposition Division of the
European Patent Office posted 14 July 2008
rejecting the opposition filed against European
patent No. 1123058 pursuant to Article 101(2)
EPC.**

Composition of the Board:

Chairman: D. Valle
Members: C. Körber
M. J. Vogel

Summary of Facts and Submissions

I. The appellant (opponent) lodged an appeal on 27 August 2008 against the decision of the Opposition Division posted on 14 July 2008 to reject the opposition. The fee for the appeal was paid on the same day and the statement setting out the grounds for appeal was received on 3 November 2008.

II. The opposition was based on Article 100(a) and (c) EPC.

III. The following documents are relevant for the present decision:

D3 = DE-A-2 627 679

D4 = US-A-4 492 231

D5 = US-A-5 810 811

D6 = EP-A-0 640 317

D7 = EP-A1-0 640 315.

IV. Oral proceedings took place on 10 August 2011.

The appellant requested that the decision under appeal be set aside and that the patent be revoked.

The respondent (patentee) requested that the appeal be dismissed (main request) or that the patent be maintained on the basis of auxiliary request 1 filed with letter of 23 May 2008 or on the basis of one of the four auxiliary requests filed with letter of 9 June 2011.

V. Claim 1 of the main request (as granted) reads as follows:

"A removable electrode assembly (21) for use with a forceps (20) having opposing end effectors (22, 24) and a handle (16, 18) for effecting relative movement of the end effectors with respect to one another, the electrode assembly comprising:

a housing (71) having at least one portion which is removably engageable with at least a portion of the forceps;

a pair of electrodes (110, 120) having opposing tissue sealing surfaces (116, 126), the electrodes being removably engageable with the end effectors of the forceps such that the tissue sealing surfaces are disposed in opposing facing spaced relation to one another, the electrodes being adapted for connection to a source of electrosurgical energy; and

at least one stop member (106) for controlling the distance between the opposing tissue sealing surfaces to be within a range from 25 to 150 μm (0.001 to 0.006 inches) such that, upon electrosurgical activation, tissue held between the tissue sealing surfaces seals into a fused mass."

Independent claim 11 of the main request reads as follows:

"A bipolar electrosurgical instrument for sealing vessels comprising:

first and second opposing effectors (222) each end effector has an inner surface and an outer surface;

a handle (226) disposed proximal of the first and second end effectors, the handle being movable from a

first position wherein the first and second end effectors are disposed in spaced relation to one another to a second position such that the end effectors hold tissue therebetween for application of electrosurgical energy, the handle including at least one gripping portion (234) to be gripped by a user to move the handle between the first position and the second position;

a first electrode disposed on the first end effector and a second electrode disposed on the second effector such that the movement of the handle from the first position to the second position results in the first and second electrodes being closed relative to each other, the electrodes residing in substantially opposing facing relation to one another and each electrode having a tissue contacting surface to engage tissue between the tissue contacting surfaces of the first and second electrodes and to enable the supply of electrosurgical energy to the tissue engaged therebetween to effect sealing;

a connector (315) for electrically connecting the first and second electrodes to a source for supplying electrosurgical energy to each of the electrodes such that one of the electrodes has a first electrical potential and the other electrode has a second electrical potential such that the substantially opposing electrodes are capable of conducting bipolar energy through tissue held therebetween; and characterized by

at least one stop member (106) for controlling the distance between the opposing tissue sealing surfaces to be within a range from 25 to 150 μm (0.001 to 0.006 inches) such that, upon electrosurgical activation,

tissue held between the tissue sealing surfaces seals into a fused mass."

VI. The appellant argued essentially as follows.

The main request contained extended subject-matter. The original disclosure contained the feature that the distance between the opposing tissue-sealing surfaces was within a range from 0.001 to 0.006 inches. The granted claims on the other hand claimed a range from 25 to 150 μm . This latter range was different from that disclosed, since the disclosed range from 0.001 to 0.006 inches corresponded to a range in metric units from 25.4 to 150.4 μm .

The subject-matter of claims 1 and 11 of the main request did not involve an inventive step and it was possibly not even novel.

The subject-matter of claim 11 was anticipated by the teaching of D6, which was acknowledged to contain the closest state of the art, combined with the general knowledge of the person skilled in the field, and/or the teaching of D5, D3, D4, D7.

The only matter of contention was whether the following features of claim 11 were disclosed in D6 or - if not disclosed - whether they were suitable to make in combination with the remaining features of the claim the subject-matter of the claim not obvious:

(1) that the electrodes reside in substantially opposing facing relation to one another and

(2) the distance range is 25 to 150 μm (0.001 to 0.006 inches) such that, upon electrosurgical activation, tissue held between the tissue sealing surfaces seals into a fused mass.

Regarding feature (1), the expression "substantially opposing facing relation" was first of all vague. It was clear that the electrodes should stay in a substantially opposing facing relation in order to work. D6 and D5, Figure 13 disclosed electrodes in substantially opposing facing relation. D7, Figure 6 disclosed electrodes 51, 54 lying exactly face to face.

Regarding feature (2), it belonged to the general knowledge of the person skilled in the field to choose a distance range of the sealing surfaces suitable to seal the tissue. The range should furthermore be adapted to the thickness of the tissue to be sealed. The claimed range was partially disclosed by D5, Figure 22 in combination with column 7, lines 27 to 33 of the description, where it was written that the gap G between the sealing surfaces was between 0.0 and 0.020, preferably 0.001 inches. D3, paragraph bridging pages 6 and 7, disclosed that the gap could be adjusted. D4, column 7, lines 13, 14 disclosed a gap (stop) much less than 1 mm.

The same considerations could be developed for claim 1 of the main request.

During the oral proceedings the appellant did not elaborate on the further attack against the inventive step of claims 1 and 11 starting from D5 as the closest

state of the art, which was presented in the written submissions.

- VII. The respondent contested the arguments of the appellant and argued in particular that the main request did not contain any extended subject-matter and that the subject-matter of claims 1 and 11 of the main request involved an inventive step.

Reasons for the Decision

1. The appeal is admissible.
2. Main request
 - 2.1 Extended subject-matter

Claims 1 and 11 of the main request do not contain extended subject-matter. The range of values for the distance between the opposing tissue sealing surfaces of 25 to 150 μm is correct within the degree of precision of the originally disclosed range (0.001 to 0.006 inches). The Board is of the opinion that a possible deviation in the sub- μm range is of no technical relevance in the field. Therefore Article 123(2) EPC is met.

- 2.2 Inventive step of claim 11
 - 2.2.1 Starting from D6

D6 discloses a bipolar electrosurgical instrument for cauterization, coagulation and/or tissue welding

comprising first and second opposing effectors (332, 334, Figure 13) each end effector having an inner surface and an outer surface; a handle (see Figure 2) disposed proximal of the first and second end effectors, the handle being movable from a first position wherein the first and second end effectors are disposed in spaced relation to one another to a second position such that the end effectors hold tissue therebetween for application of electrosurgical energy, the handle including at least one gripping portion to be gripped by a user to move the handle between the first position and the second position; a first electrode disposed on the first end effector and a second electrode disposed on the second end effector (column 11, lines 33 to 35) such that the movement of the handle from the first position to the second position results in the first and second electrodes being closed relative to each other, each electrode having a tissue contacting surface to engage tissue between the tissue contacting surfaces of the first and second electrodes and to enable the supply of electrosurgical energy to the tissue engaged therebetween; a connector for electrically connecting the first and second electrodes to a source for supplying electrosurgical energy to each of the electrodes such that one of the electrodes has a first electrical potential and the other electrode has a second electrical potential such that the electrodes are capable of conducting bipolar energy through tissue held therebetween and at least one stop member (29, Figure 3) for controlling the distance between the opposing tissue-sealing surfaces to be within a range from 0.012 and 0.022 inches (column 8, lines 11 to 13; column 9, lines 8 to 15).

However, D6 does not disclose that:

- (1) the electrodes reside in substantially opposing facing relation to one another (see by contrast Figures 13 and 17 of D6) and that:
- (2) the distance range is 25 to 150 μm (0.001 to 0.006 inches) such that, upon electrosurgical activation, tissue held between the tissue-sealing surfaces seals into a fused mass.

D6 does not disclose feature 1. Figure 13 of D6 does not disclose, in particular, electrodes in substantially facing relationship. On the contrary, the negative lower electrode is outwardly displaced with respect to the upper positive electrode. D6 does not disclose the claimed range for the distance of feature 2 either. It does not belong to the general knowledge of the person skilled in the field to choose a range of values for the distance as claimed. The explicit disclosure of a different range (at least twice as much as the upper limit of the claimed range) in D6 itself speaks against it.

The purpose of the invention has therefore to be seen in providing an electrosurgical instrument which guarantees a satisfactory sealing of well-delimited areas of biological tissue-forming vessels into a fused mass, see the claim, last feature, and description, column 2, lines 29 to 34. The aim of the invention is to achieve sealing of the vessels. Sealing means - in the sense of the invention (see column 2, lines 29 to 34) - liquefying the collagen in the tissue so that it cross-links and reforms into a fused mass. Sealing is

different from coagulation, which consists in desiccation and rupture of the tissue cells (see column 2, lines 25 to 29). Coagulation may be sufficient to close small vessels. However, larger vessels need to be sealed to assure permanent closure.

This purpose is achieved by the above-cited distinguishing features 1) and 2). In the view of the Board the gist of the invention lies in having recognized that in the usual size range of large vessels of the body which need to be treated by sealing, sealing can be achieved by pressing their tissue between the electrodes in substantially opposing facing relation to one another and leaving a defined gap between the tissue-sealing surfaces having a relatively narrow value range from 25 to 150 μm (0.001 to 0.006 inches), see description, column 2, lines 46 to 50.

Figure 6 of D7 discloses feature 1. D5, Figure 22, column 7, lines 27 to 33, discloses a range comprising the range of the invention (gap G between 0.0 and 0.020, preferably 0.001 inches, i.e. the lower limit value of the claimed range). The Board is, however, of the opinion that the subject-matter of claim 11 involves an inventive step having regard to the teaching of D6, D5 and D7. It is not sufficient to pick and choose from the state of the art some suitable features in order to form a successful attack against the inventive step of the claim. For that, it is essential to have in the state of the art some hints in the direction of the specific combination claimed, in particular in a case such as the present case, in which the distinguishing features present a synergy effect.

The Board has further observed that the opposed prior art is strongly focused on devices using staples. On the other hand, the invention claimed does not require using staples, even if stapling is mentioned in the description, though never as being of the essence for the invention. The Board believes that a precise size of the gap is not important in devices using staples. This view is based on a joint consideration of the documents D5, D6 and D7, all originating from the same inventor. These documents disclose greatly differing values for the gap: D5: 0.0 and 0.020, preferably 0.001 inches (column 7, lines 31 to 33), or 0.001 to 0.045 inches (column 4, lines 5 to 7), D6: 0.012 to 0.022 inches (0.304 to 0.558 mm, column 9, lines 13 to 15); D7: 1.5 to 2.00 mm (0.059 to 0.078 inches, column 8, lines 10 to 11. Furthermore, the disclosed ranges are in general remarkably broader than that of the invention.

D3 and D4 are not relevant for an evaluation of the inventive step of claim 11 since they deal with tweezers. Tweezers generally have flexible blades, which goes against the purpose of the invention of maintaining well defined tissue-handling conditions between the sealing surfaces.

2.2.2 Starting from D5

D5 discloses a bipolar electrosurgical instrument for coagulating vessels comprising first and second opposing effectors (332, 334, Figure 13) each end effector having an inner surface and an outer surface; a handle (Figure 2) disposed proximal of the first and second end effectors, the handle being movable from a

first position wherein the first and second end effectors are disposed in spaced relation to one another to a second position such that the end effectors hold tissue therebetween for application of electrosurgical energy, the handle including at least one gripping portion to be gripped by a user to move the handle between the first position and the second position; a first electrode (352) disposed on the first end effector (334) and a second electrode disposed on the second end effector such that the movement of the handle from the first position to the second position results in the first and second electrodes being closed relative to each other, each electrode having a tissue contacting surface to engage tissue between the tissue contacting surfaces of the first and second electrodes and to enable the supply of electrosurgical energy to the tissue engaged therebetween to effect sealing; a connector for electrically connecting the first and second electrodes to a source for supplying electrosurgical energy to each of the electrodes such that one of the electrodes has a first electrical potential and the other electrode has a second electrical potential such that the substantially opposing electrodes are capable of conducting bipolar energy through tissue held therebetween.

However, D5 does not disclose that:

- (1) the electrodes reside in substantially opposing facing relation to one another and
- (2) at least one stop member for controlling the distance between the opposing tissue sealing surfaces to be within a range from 25 to 150 μm (0.001 to 0.006 inches) such that, upon electrosurgical activation,

tissue held between the tissue sealing surfaces seals into a fused mass.

D5 discloses further that the distance between the opposing tissue sealing surfaces is within a range from 0.0 to 0.020, preferably 0.001 inches, see D5, column 7, lines 27 to 33. D4 discloses a gap range "much less than 1 mm", see column 7, lines 43 to 47. Furthermore, D3 discloses a stop member (column 7, last paragraph). However a combination of D5 with D3 and D4 in the form of claim 1 is not obvious since D5 concerns essentially staplers, whereas D3 and D4 relate to tweezers (see the corresponding reasoning in the previous point).

2.3 Inventive step of claim 1

The test for inventive step of claim 1 leads essentially to the same considerations as for claim 11.

2.4 Accordingly, the subject-matter of claims 1 and 11 is based on an 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:

D. Sauter

D. Valle