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Datasheet for the decision of 26 January 2011

Case Number: T 0216/08 - 3.2.02

Application Number: 03012523.1

Publication Number: 1362555

IPC: A61B 17/32

Language of the proceedings: EN

Title of invention:
Ultrasonic clamp coagulator apparatus having improved waveguide support member

Patentee:
ETHICON ENDO-SURGERY, INC.

Opponent:
Schmiedl, Roland, Prof. Dr.

Headword:
-

Relevant legal provisions:
EPC Art. 56, 76(1), 123(2)
RPBA Art. 12(2), 13(1)

Relevant legal provisions (EPC 1973):
-

Keyword:
"Extension of subject-matter (yes)"
"Inventive step (no) - first auxiliary request"

Decisions cited:
-

Catchword:
-

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Case Number: T 0216/08 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 26 January 2011

Appellant: (Opponent)
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Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted 21 November 2007 concerning maintenance of European patent No. 1362555 in amended form.**

Composition of the Board:

Chairman: M. Noël
Members: D. Valle
A. Pignatelli

Summary of Facts and Submissions

I. The appellant (opponent) lodged an appeal by notice received on 22 January 2008 against the interlocutory decision of the Opposition Division posted on 21 November 2007 to maintain the European patent No. 1 362 555 in amended form. The fee for appeal was paid on the same day. A statement setting out the grounds for appeal was received on 20 March 2008.

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

D2: JP - 8-275948
D3: JP - 8-275951.

III. Oral proceedings took place on 26 January 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 or that the patent be maintained in amended form on the basis of the set of claims 1 to 17 according to one of the first to third auxiliary requests, all filed with letter dated 10 December 2008.

IV. Claim 1 of the main request reads as follows (letters (a) to (g) added by the Board for ease of reference):

"An ultrasonic surgical clamp apparatus (120) comprising:
(a) a housing (130),

an outer tubular sheath (160) having a proximal end joined to

(b) said housing (52) and a distal end;

(c) an inner actuating member (170) reciprocally positioned within said outer tubular sheath (160);

(d) an ultrasonic waveguide (180) positioned within said outer tubular sheath (160) and having an end-effector (180') extending distally of said distal end of said outer tubular sheath (160), said actuating member being reciprocable relative to said waveguide (180);

(e) a clamp arm (190) pivotally mounted on said distal end of said outer tubular sheath (160) for pivotal movement with respect to said end-effector (180') for clamping tissue between said clamp arm (190) and said end-effector (180'), said clamp arm (190) being operatively connected to said actuating member (170) so that reciprocal movement of said actuating member (170) pivotally moves said clamp arm (190) with respect to said end-effector (180');

(f) wherein the proximal end of the outer tubular sheath (160) is rotatably joined to the housing (130), and the inner actuating member (170) and clamp arm (190) and the ultrasonic waveguide (180) are arranged for rotation with the outer sheath (160) with respect to said housing (130);

characterized in that

(g) said inner actuating member (170) is tubular, said waveguide (180) being positioned therewithin."

Claim 1 of the first auxiliary request differs from claim 1 of the main request in that in feature (f) the

expression "arranged for rotation" is replaced by the expression "mounted for rotation together".

Claim 1 of the second auxiliary request contains all features of claim 1 of the main request with the following feature added at the end of the claim:

(h) "and said clamp arm is pivotally mounted at its distal end and comprises at least one lever portion at its proximal end, said at least one lever portion being operatively connected to said actuating member".

Claim 1 of the third auxiliary request contains all features of claim 1 of the first auxiliary request and the same additional feature (h) as for the second auxiliary request.

V. The appellant argued as follows.

D3 should be introduced into the appeal proceedings because it was filed as a direct reaction to the contested decision and was highly relevant. D3 disclosed in particular that the clamp arm was pivotally mounted on the outer tubular sheath.

The expression "arranged for rotation" contained in claim 1 of the main and the second auxiliary requests was not originally disclosed in the parent application, thereby extending the claimed subject-matter.

The subject-matter of claim 1 of the first auxiliary request did not involve an inventive step having regard to the teaching of D3 and D2 taken in combination. In

particular, D2 disclosed a tubular actuating member and a waveguide positioned therewithin, the features which were missing in D3.

The admissibility of claim 1 of the third auxiliary request was questionable, due to lack of clarity and support of both expressions "at its distal end" and "connected to" in the last, additional feature (h).

VI. The respondent argued as follows.

D3 should not be admitted into the proceedings because it was filed belatedly and was not prima facie relevant. This document was already known by the appellant and could have been submitted earlier in the first instance proceedings. The appeal procedure was not meant to give the appellant further possibilities of introducing new arguments in connection with new documents, which could be seen as a fresh ground for opposition.

The wording "arranged for rotation" contained in claim 1 of the main and the second auxiliary requests was directly and unambiguously derivable from the parent application. By this wording, the skilled person would understand an arrangement in which the rotation of the different components corresponds with that of the outer sheath. But an arrangement wherein the sheath did not rotate with the other components would also be considered by a skilled person to be originally disclosed. Therefore the above wording is appropriate to properly define the invention, in accordance with the requirements of Articles 76(1) and 123(2) EPC.

Exact correspondence with the terms used in the application is not required by the EPC.

A combination of the teachings of D3 and D2 would not lead in an obvious manner to the subject-matter of claim 1 of the first auxiliary request.

D3 failed to disclose a tubular actuating member for pivoting the clamp arm and a waveguide positioned therewithin. In D3 the drive shaft was not disclosed clearly enough. It was questionable whether it could be rotated with respect to the housing because it was prevented from doing so by a pin, as shown in Figure 4. Moreover, the embodiment according to Figures 4 to 6 would not allow reducing the cross-sectional area at the distal end of the clamp coagulator since there was no room left for inserting a tubular drive shaft, as Figure 5 made clear.

In D2 the actuating member did not reciprocate within the outer tubular sheath since the moving part of the clamp arm was biased in an open position by a spring, i.e. the actuator was only used to urge the clamp into the closed position. Moreover the clamp was pivotally mounted on the waveguide, not onto the outer sheath. There was no motivation for combining the teachings of documents D3 and D2 and even if this had been so, a number of modifications still would have been necessary to arrive at the claimed solution.

The features (h) added to claim 1 of the third auxiliary request were based on Figure 2 and the text referred to from page 17, line 19 to page 20, line 14 of the application as filed. The feature of the clamp

arm being pivotally mounted "at its distal end" was the consequence of an obvious error, which could be easily rectified into "at its proximal end". The feature of at least one lever portion being "operatively connected to" the actuating member was to be construed as meaning "in operative engagement with". As a whole, the added features aimed at better distinguishing the claimed subject-matter over the construction disclosed in D2.

Reasons for the Decision

1. Admissibility of document D3

The admissibility of a late-filed submission is to be decided at the Board's discretion under Article 114 EPC and Article 13(1) RPBA.

Document D3 was filed by the appellant with its statement setting out the grounds of appeal and in direct reaction to the arguments put forward by the first instance in the contested decision.

This document, therefore, was submitted as soon as possible and within the framework of the appellant's complete case, as required by the provisions of Article 12(2) RPBA. Moreover, since D3 is regarded by the Board as being prima facie highly relevant, this document is admitted into the appeal proceedings.

2. Main and second auxiliary requests - amendments

The expression "arranged for rotation" in feature (f) is neither disclosed in the divisional application as filed nor in the earlier (parent) application from which the divisional originates. This expression was in fact introduced for the first time by the applicant/respondent with letter of 2 June 2003, along with an amended set of claims 1 to 17 submitted for examination in replacement of claims 1 to 14 originally filed. Therefore, the wording "arranged for rotation" is not supported by either of the applications as originally filed.

The most appropriate wording for characterising the rotational relationship between the outer tubular sheath 160, the inner tubular actuating member 170 and the ultrasonic waveguide 180 (which is part of the clamping mechanism) with respect to the housing 130, is given by the expression "mounted for rotation together". A basis for this expression is to be found on page 3, lines 18 to 20 and Figure 4 of the divisional application as filed. This expression is to be understood as the conjoint rotation of the different elements taken as a unit, as more specifically described on page 16, lines 1 to 4 and from page 18, line 28 to page 19, line 8 of the divisional application as filed. Moreover, since the clamp arm 190 (which is also part of the clamping mechanism) is pivotally connected to the outer tubular sheath (cf. page 17, lines 19 to 24), said clamp arm is also comprised in the rotating unit.

The wording "arranged for rotation" is broader than "mounted for rotation together" since the former means simply "rotatable", i.e. having a possibility for each element of the assembly to rotate independently of one or more of the other elements, which is not envisaged or derivable from any of the quoted passages of the description. In the Board's view the above amendment amounts to unacceptably extending the claimed subject-matter beyond the content of the application as filed, in violation of the requirements of Article 123(2) EPC.

Since, moreover, the expression at issue was not supported by the parent application either, the description and drawings of which are identical to those of the divisional application, the amendment also contravenes the requirements of Article 76(1) EPC.

It results therefrom that claim 1 of the main request is not allowable due to unacceptable extension of its subject-matter under Articles 76(1) and 123(2) EPC.

Since claim 1 of the second auxiliary request contains the contested expression, the same conclusion as above applies to this request.

3. First auxiliary request - inventive step

With the words of claim 1 at issue, document D3 (see in particular the second embodiment shown in Figures 4 to 6 and the English translation of the text concerning these figures) discloses an ultrasonic surgical clamp apparatus comprising a housing, an outer tubular sheath (insertion part 3) having a proximal end joined to said housing and a distal end; an inner actuating member in

the form of a drive shaft (not shown but identified on page 15, lines 8-10), reciprocally positioned within said outer tubular sheath; an ultrasonic waveguide (probe 61) positioned within said outer tubular sheath and having an end-effector extending distally of said distal end of said outer tubular sheath 3 (see Figure 5), said actuating member being reciprocable relative to said waveguide (page 15, lines 2 to 10). Moreover, a clamp arm (gripping member 71) is pivotally mounted on said distal end of said outer tubular sheath 3 (Figure 5) for pivotal movement with respect to said end-effector for clamping tissue between said clamp arm and said end-effector (paragraph bridging pages 14 and 15). Furthermore, the clamp arm is operatively connected to the actuating member so that reciprocal movement of said actuating member pivotally moves said clamp arm with respect to said end-effector (page 15, lines 4 to 10). Further, the proximal end of the outer tubular sheath is rotatably joined to the housing through a rotation ring 12 (page 9, last paragraph) and, as a consequence, the inner actuating member, the clamp arm and the ultrasonic waveguide are mounted for rotation together with the outer sheath with respect to said housing. The drive pin referred to at the top of page 15 of D3 is part of the reciprocable mechanism for actuating the clamp arm, but this does not exclude rotation of the drive shaft together with the other elements. Therefore, D3 discloses all the features of the pre-characterising portion of claim 1.

However, D3 does not disclose feature (g) of the characterising portion, according to which said inner actuating member is tubular, said waveguide being positioned therewithin.

The technical problem underlying these distinguising features is to provide a clamp coagulator for an ultrasonic surgical instrument particularly suited for endoscopic applications, i.e. having a relatively small cross-section, as recited in paragraph [7] of the patent in suit. This problem is however well known in the relevant surgical field as being part of the constant endeavour to find means for less invasive surgery.

Looking around for suitable solutions, the skilled person would consider document D2, which belongs to the same technical field as that of the invention and discloses the characterising features (g) of claim 1, i.e. a tubular inner actuating member and a waveguide positioned therewithin.

More specifically, D2 (see Figures 2 to 5 and the text referred to in paragraphs [16] to [21] of the English translation) discloses a clamping arm 12 pivotally mounted on a base member 15 connected (snap-fit connection) to a reduced diameter section 17 of an ultrasonic waveguide 4 (probe). The clamp arm is biased in its open position by a spring 13 and actuated in its closed position by sliding a tubular inner sheath 19,20 (actuating member) positioned within a tubular outer sheath 5. The waveguide is itself positioned within the inner sheath as clearly shown in Figure 5.

Therefore, D2 discloses the characterising features (g) of claim 1 which were missing in D3.

Contrary to the assertion of the respondent, the sliding section 20 of the actuating member reciprocates in order first to bring the moving part 12 of the clamping mechanism into the closed position and then to release the same. It matters little what means are used for opening the clamp arm (a biasing spring in D2 or lever portions 193 in the patent in suit) since those specific means are not the subject of claim 1. Similarly, other differentiating features of D2 put forward by the respondent, such as mounting the clamping arm on the waveguide instead of on the outer sheath are irrelevant since all the features of claim 1 other than features (g) are already known from the closest prior art document D3.

D2, therefore, suggests a solution suitable for the above technical problem. For the assessment of inventive step, novelty of the problem is not required by the EPC. Neither is it required that the problem should be mentioned in or derivable from the prior art documents. Starting from the ultrasonic surgical clamp apparatus known from D3, the mere observation of Figure 5 of D2 is sufficient to suggest using a tubular actuating member surrounding the waveguide, thus directly arriving at the rather functional definition of the claimed subject-matter, with the associated advantage of reducing the cross-sectional area of the endoscopic portion of the clamp coagulator.

Therefore the subject-matter of claim 1 of the first auxiliary request does not involve an inventive activity having regard to the combination of the teachings of D3 and D2.

4. Third auxiliary request - amendments

The feature (h) added to claim 1 of the third auxiliary request include that (i) the clamp arm is pivotally mounted at its distal end and (ii) at least one lever portion of the clamp arm is operatively connected to the actuating member.

While feature (i) results from an evident error, which could have been easily rectified into "at its proximal end" as shown in Figure 2 of the patent, feature (ii) has no basis in the application as filed.

On page 18, lines 5 to 10 of the application, the lever portions are said to be positioned in "operative engagement" with the reciprocable actuating member, as illustrated in Figure 2.

Such releasable engagement means is not to be equated to connecting means used e.g. for permanently connecting the clamp arm to the outer sheath (cf. page 17, lines 21 to 24). In the Board's view these two links are functionally different and, therefore, not equivalent.

It results that the amendments made to claim 1 of the third auxiliary request extend its subject-matter beyond the content of the application as filed, in contravention of the requirements of Article 123(2) EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairman:

S. Sánchez Chiquero M. Noël