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Datasheet for the decision of 18 September 2012

Case Number: T 0619/10 - 3.2.02

Application Number: 07250483.0

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IPC: A61B 17/02, A61B 17/072, A61B 17/00, A61B 17/10, A61B 17/32

Language of the proceedings: EN

Title of invention:
Apparatus for performing trans-anal resection

Applicant:
ETHICON ENDO-SURGERY, INC.

Opponent:
-

Headword:
-

Relevant legal provisions:
EPC Art. 56
RPBA Art. 15(3)

Keyword:
"Inventive step (no)"

Decisions cited:
-

Catchword:
-

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Case Number: T 0619/10 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 18 September 2012

Appellant: (Applicant)
ETHICON ENDO-SURGERY, INC.
4545 Creek Road
Cincinnati, Ohio 45242 (US)

Representative:
Tunstall, Christopher Stephen
Carpmaels & Ransford
One Southampton Row
London WC1B 5HA (GB)

Decision under appeal:
Decision of the Examining Division of the European Patent Office posted 29 October 2009 refusing European patent application No. 07250483.0 pursuant to Article 97(2) EPC.

Composition of the Board:

Chairman: E. Dufrasne
Members: P. L. P. Weber
C. Körber

Summary of Facts and Submissions

I. The appeal of the applicant is against the decision of the Examining Division posted on 29 October 2009 to refuse the application for lack of inventive step.
The Examining Division found the subject-matter according to claim 1 to lack an inventive step over a combination of D1 (US-A-2005/0143759) and D2 (EP-A-1183991).

II. Claim 1 on which the decision is based reads as follows:

"1. A surgical kit adapted for the performance of trans-anal resection, the surgical kit comprising:
a surgical instrument (20) comprising a frame having a proximal end and a distal end, with a handle (21) positioned at the proximal end and an end effector (80) positioned at the distal end, the end effector being shaped and dimensioned for supporting a cartridge module (120), a firing mechanism is associated with the end effector and the cartridge module for selective actuation, and wherein the end effector has a radius of curvature optimized for a trans-anal resection such that the end effector has a curvature of at most approximately a 40 mm diameter, and
a dilator (224) having an opening with a curvature of at most approximately a 40 mm diameter."

III. The notice of appeal was filed on 7 January 2010 and the appeal fee paid on the same day.
The statement setting out the grounds of appeal was filed on 8 March 2010.

IV. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the version taken as a basis for the decision under appeal. Auxiliarly, oral proceedings were requested.

V. With letter of 19 March 2012 the Board summoned the appellant to oral proceedings. In the annex to the summons the Board expressed the provisional opinion that the subject-matter of claim 1 did not involve any inventive step.

VI. With letter of 21 May 2012 the appellant submitted additional arguments as to why the subject-matter of claim 1 would involve an inventive step.

VII. With letter of 14 June 2012 the appellant informed the Board that it would not be represented at the oral proceedings.

VIII. On the same day the Board informed the appellant that the oral proceedings were cancelled and that the appellant would be treated as relying on its written case (Article 15(3) RPBA).

IX. The arguments of the appellant can be summarised as follows:

The person skilled in the art would not have been prompted to combine Dl and D2 to arrive at the kit according to claim 1. The claimed kit is for trans-anal resection (TAR) and is the combination of a stapler with a head of a particular curvature and a dilator whose curvature is adapted to that of the stapler head.

Dl was directed to lower anterior resection (LAR) (see page 2, paragraph 35) and not to trans-anal resection (TAR) like the invention. That meant that the device of Dl was designed to be pushed down into the pelvis via an abdominal incision, without need for an anal dilator, whereas in trans-anal resection the device was inserted into the rectum through the anus. For LAR the stapler had to be of much larger dimension than for TAR, because it was very cumbersome to introduce the stapler several times into the pelvis. Conversely, in TAR, the dimension was limited by the dilation possibility of the anus. It was not because D1 disclosed a dimension of the diameter of curvature (one inch) allowing the stapler to be used in TAR that the person skilled in the art would be prompted by D1 to use the stapler for TAR. On the contrary, the person skilled in the art would consider that the curvature of a diameter ranging from 25.4 mm to 40 mm was outside what would normally be used for LAR, and would therefore not seriously contemplate applying the teaching of D1 for such values. The person skilled in the art would equally not have any reason to combine a stapler for LAR with a dilator for the anus, let alone that disclosed in D2.

The anoscope of D2 had a blind longitudinal opening (3) and a solid tip (10) at its distal end. The lateral opening (3) from where tissue could be exposed to resection was not suitable for TAR because this would require turning the anoscope in order to reach all the tissue portions to be resected. This would go against the usual procedure for TAR which foresees that the anoscope had to be fixed to the anus wall, see Figures 11 to 16 of the application.

Thus, the subject-matter according to claim 1 involves an inventive step and the appeal has to be allowed.

Reasons for the Decision

1. The appeal is admissible.

2. Disclosure of D1

2.1 It is undisputed that D1 discloses a surgical instrument having most of the features of the surgical instrument of claim 1.

Dl namely discloses a surgical instrument (20) comprising a frame having a proximal end and a distal end, with a handle (21) positioned at the proximal end and an end effector (80) positioned at the distal end, the end effector being shaped and dimensioned for supporting a cartridge module (120), a firing mechanism is associated with the end effector and the cartridge module for selective actuation, and the end effector has a radius of curvature (Figure 1 (very similar to Figure 1 of the present application) and corresponding description).

It is also undisputed that in D1 there is an indication of the value of the diameter of curvature in paragraph [0036]:

"*...More particularly, the end effector 80 has a curvature with a diameter between approximately one inch and approximately four inches, and more preferably*

between approximately two inches and approximately four inches. In accordance with a more preferred embodiment, the end effector 80 has a curvature with a diameter of approximately 3 inches."

The first interval mentioned (one inch to four inches, that is 25.4 mm to 101.6 mm) thus encompasses values below the 40 mm mentioned in the claim.

2.2 The appellant submits that the person skilled in the art would not seriously contemplate building an end effector with a curvature of a diameter ranging between 25.4 mm and 40 mm because the person skilled in the art would not use such a small dimension for LAR.

The Board does not share this opinion. Eliminating the whole range from 25.4 mm to 40 mm would amount to eliminating a substantial part (around 20%) of the interval disclosed. In D1 there is however no particular drawback mentioned for small values of the diameter of curvature. For the person skilled in the art reading D1, there is hence no particular reason to avoid building an end effector having such dimensions; on the contrary, this is part of the teaching of D1. Furthermore the mention of the end values of the intervals is preceded by the word "approximately" which is an indication that the author of D1 even contemplated building end effectors with diameters of curvature smaller than one inch.

2.3 Hence, in the Board's opinion, a surgical instrument of the kind claimed with an end effector having a curvature of a diameter below 40 mm is disclosed by D1.

2.4 In addition, the only feature which makes such a stapler suitable - or not - for TAR is the diameter of its curvature. No other feature was mentioned by the appellant which would (possibly) differentiate a stapler for LAR from that for TAR.
Hence, the person skilled in the art knows that as soon as the diameter of curvature is appropriate the stapler is also for use in TAR. Consequently there can be no doubt that for the person skilled in the art a stapler as described in D1 and having a diameter of curvature below 40 mm is (also) a stapler for TAR.

2.5 Finally, surgical stapling instruments are disclosed in D1 ([0005]) as commonly used to extend the transluminal exploitation of mechanical suturing devices introduced in particular into the anal canal, which also shows the person skilled in the art that D1 is not limited to LAR staplers.

2.6 Therefore, a surgical instrument adapted for the performance of TAR according to claim 1 is known from D1.

3. Differentiating feature

3.1 However, Dl does not disclose a surgical kit made of a surgical instrument as claimed in claim 1 and a dilator having an opening with a curvature of at most approximately a 40-mm diameter adapted for the performance of TAR. It is to be noted here that the diameter of curvature of the opening is the only feature defining the claimed dilator.

3.2 It is state of the art that for a TAR to be performed, the anus has to be dilated and remain dilated during the whole surgical operation. In other words a surgeon will always have at his disposal a dilator to dilate the anus before introducing a surgical instrument for performing any resection within the rectum. It is also self-evident that the opening obtained by dilation of the anus should not over-expand the latter but must be large enough to allow the surgical instrument to be introduced into the rectum.
In other words, there must be some adequation between the size of the opening created by the dilator and the size of the surgical instrument used.
Thus, it is state of the art that in the operating room the surgeon has at his disposal a dilator and a surgical instrument able to be introduced through the dilator into the rectum, i.e. a dilator and a surgical instrument compatible with each other.

3.3 The appellant now proposes to provide these two elements in the form of a surgical kit.

The only effect of the provision of such kit can be seen in a possibly better guarantee of adequation between the size of the surgical instrument and the size of the dilator opening, and hence also in a time saving during preparation of the operating room.

4. The objective problem can thus be seen in improving the preparation of the operating room.

5. The improvement of efficiency is a constant desire of the person skilled in the art, and in this context the provision of a kit comprising the two elements, i.e. a

ready-to-use kit containing the two known parts for the performance of TAR, can however not be considered to involve any inventive step. As mentioned further above the surgeon is used to having a dilator adapted to the size of the surgical instrument, and it is part of the normal surgical procedure to place such a dilator before introducing the surgical instrument into the rectum. In other words, it is usual to use the surgical instrument together with a corresponding dilator to perform TAR. The mere provision of a kit of parts is a simple alternative to the separate provision of these two elements. No surprising or unexpected advantage can be seen in the provision of such a kit. It is obvious that the provision of a kit of parts saves time as compared to the separate provision of the individual parts composing the kit. The presently claimed kit does not go beyond this well-known basic advantage of ready-to-use-kits.

Further, it is to be noted that the claim does not define any other feature of the dilator than the diameter of its opening curvature and that this diameter has to be adapted to the size of the surgical instrument to be introduced into the rectum. This is however the most usual and even unavoidable way to proceed. It would not make any sense to use a dilator and a surgical instrument which are not adapted to each other. The claim does nothing other than define an obvious combination.

In such a situation, whether the dilator according to D2 is particularly adapted or not, as submitted by the appellant, for use with a surgical instrument according to D1 is not decisive. D2 is a document simply

supporting that anus dilators or anoscopes existed, that it was usual to use them in relation to surgical operations in the rectum (see paragraphs [0001] to [0004] of D2), and that they had dimensions adapted to the corresponding surgical instrument.

6. Hence, the subject-matter of claim 1 does not involve any inventive step within the meaning of Article 56 EPC so the appeal must be dismissed.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

D. Hampe E. Dufrasne