

Internal distribution code:

- (A) [] Publication in OJ
(B) [] To Chairmen and Members
(C) [X] To Chairmen
(D) [] No distribution

D E C I S I O N
of 27 August 2002

Case Number: T 0760/99 - 3.2.2

Application Number: 90305058.1

Publication Number: 0399701

IPC: A61B 17/072

Language of the proceedings: EN

Title of invention:
Surgical stapling apparatus

Patentee:
United States Surgical Corporation

Opponent:
ETHICON ENDO-SURGERY, INC.

Headword:
-

Relevant legal provisions:
EPC Art. 123(2), 84, 56

Keyword:
"Adequate support, clarity and inventive step (yes, after amendment)"

Decisions cited:
-

Catchword:
-



Case Number: T 0760/99 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 27 August 2002

Appellant: ETHICON ENDO-SURGERY, INC.
(Opponent) 4545 Creek Road
Cincinnati
Ohio 45242-2839 (US)

Representative: Mercer, Christopher Paul
Carpmaels & Ransford
43, Bloomsbury Square
London WC1A 2RA (GB)

Respondent: United States Surgical Corporation
(Proprietor of the patent) 150 Glover Avenue
Norwalk
Connecticut 06856 (US)

Representative: Marsh, Roy David
Hoffmann, Eitle
Patent- und Rechtsanwälte
Postfach 81 04 20
D-81904 München (DE)

Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 3 May 1999
rejecting the opposition filed against European
patent No. 0 399 701 pursuant to Article 102(2)
EPC.

Composition of the Board:

Chairman: W. D. Weiß
Members: D. Valle
R. T. Menapace

Summary of Facts and Submissions

- I. The appellant (opponent) filed an appeal against the decision of the Opposition Division to reject the opposition.

The patent was opposed on the basis of Articles 100(a) EPC (lack of novelty and inventive step) and 100(b) EPC (insufficient disclosure).

The following documents cited during the opposition proceedings are still relevant for the present decision:

D5: SU-A-0 728 848 (translation into English)
D8: US-A-4 196 836
D9: US-A-4 562 839
D10: US-A-4 691 853
D11: US-A-4 728 020

- II. Oral proceedings were held on 27 August 2002 on request of both parties.
- III. At the end of the oral proceeding the appellant requested that the decision under appeal be set aside and the patent be revoked.

The respondent (patent proprietor) requested that the appeal be dismissed and the patent be maintained on the basis of amended claims 1 to 19 and amended pages 1 to 4 of the description, as submitted during the oral proceedings, the rest of the description and figures as granted.

IV. Claim 1 as filed during the oral proceedings on 27 August 2002 reads as follows:

"Surgical apparatus (100) for driving surgical fasteners into body tissue for adjoining two hollow organs, and comprising:

a) a frame (102);
b) an endoscopic portion defining a longitudinal axis and extending distally from said frame, said endoscopic portion including:

- i) an elongate housing (134) having a distal member (134B) for mounting a cartridge assembly (137), said cartridge assembly (137) including a plurality of surgical fasteners (138) slidably mounted therein arranged in a plurality of lines, and having a tissue-engaging surface;
- ii) an anvil member (136) having a proximal end (136C) and a fastener-forming surface (136D), and a longitudinal center groove (136F) to permit passage of a knife, said proximal end (136C) mounted to said elongate housing such that the anvil member is movable between an open position and a closed position wherein said fastener-forming surface has a plurality of fastener-forming depressions arranged in a plurality of lines and is in close co-operative alignment with said tissue-engaging surface of said cartridge assembly;
- iii) means (127, 327) for moving said anvil member between said open position and said closed position which, by distal movement moves the anvil member to its closed position and clamps tissue between the anvil member and the cartridge assembly;
- iv) independent means (129) for ejecting said

surgical fasteners from said cartridge assembly after having clamped said tissue; whereby all of said plurality of fasteners engage said fastener-forming surface in one actuation of said ejecting means; and wherein

v) the anvil member is pivotally mounted relative to the elongate housing proximally of its fastener-forming surface (136D);

and further wherein said endoscopic portion (103) having a gripping ring (424) or thumb wheel (123) at its proximal end for rotating the endoscopic portion around said longitudinal axis and relative to said frame (102)."

V. The appellant presented the following arguments:

Claim 1 did not comply with Article 123(2) EPC because it consisted of a set of features which were not originally disclosed in combination.

Furthermore claim 1 did not comply with Article 84 EPC because it attempted to define a surgical apparatus making reference to a cartridge which did not belong to the claimed apparatus. Feature b) i) referred to a "cartridge assembly including a plurality of surgical fasteners slidably mounted therein arranged in a plurality of lines". Feature b) ii) referred to the knife which was also part of the cartridge. Feature b) iii) referred to clamping tissue between the anvil member and the cartridge assembly. Feature b) iv) referred to ejecting means for ejecting the fasteners from the cartridge assembly.

Even if the above objection were not considered relevant by the Board, claim 1 would lack an inventive

step. Starting from document D4, which related - like the purported invention - to a surgical instrument for performing anastomosis (page 1, first paragraph), following features of claim 1 were in particular disclosed: two lines of staples, a knife, an anvil, and ejecting means; see page 2, last paragraph; page 3, last paragraph; page 4, paragraph starting from line 21, and last paragraph. The only relevant feature of claim 1 which was not disclosed by document D4 was a gripping ring for rotating the endoscopic portion of the instrument around the longitudinal axis and relative to said frame. This last feature was however void of any technical contribution to the invention being essentially a functional feature. There was no prejudice against providing the surgical instrument according to document D4 with a rotational mechanism, if necessary. Even if a free rotation had been considered unsafe, a rotation of the distal end could still have been realized, when coupled with a locking mechanism. Documents D8 to D11 all showed surgical instruments having a distal end which rotated relative to the proximal end. Contrary to the assertion of the respondent, claim 1 did not support the view that distal rotation entered into play only when the instrument was inserted.

VI. The respondent replied as follows:

The features added to claim 1 complied with Article 123(2) EPC because they were disclosed in the description, column 3, lines 1 to 3, 5, 25 and 31; column 2, lines 13 and 58; column 6, line 23; columns 3, 5 and 6; column 11, lines 56 to 58; column 22, line 7; and column 23, line 44.

Claim 1 also complied with Article 84 EPC. The reference to the cartridge in the claims was necessary because the instrument had to be capable to cooperate with the cartridge and therefore it should be compatible with it. Consequently, the reference to the features of the cartridge implied constructional features of the surgical apparatus opposite to the location of the fastening forming surface of the anvil.

Document D4 had been designed for open surgery anastomosis and not, like the invention, for endoscopic anastomosis. In endoscopic anastomosis the operation site was out of reach for the hands of the surgeon and therefore it was important for the instrument to give the surgeon a tactile sensibility during the fine tuning of the rotational position of the instrument tool. Being the instrument of document D4 only suitable for open surgery, the tool of the instrument had no need to be rotational. There was no sense in modifying the instrument according to document D4 to introduce a rotational mechanism. Documents D8 to D11 all disclosed the possibility to rotate the instrument tool merely for the purpose of setting up the instrument before its use and did not disclose - like the invention - the possibility of rotation "in work", that is after clamping the jaws on the parts to be joined.

Reasons for the decision

1. The appeal is admissible.
2. *Amendments*

The amendments to the claims are supported by the

passages of the description cited by the respondent (see point VI above) and restrict the extension of the protection of the claims. The amendments to the description have been made in order to adapt the description to the new filed claims.

The Board does not share the view of the appellant that the features of claim 1 are not originally disclosed in combination. The added features together with the previous ones form a coherent set from which can be derived a more precise picture of the way of working of the instrument as it was disclosed in the original application. The appellant, on the other hand, has failed to specifically point out any features which would not fit in the claimed combination.

3. *Clarity*

Claim 1 is clear. The passages referring to the cartridge, - which does not belong to the claimed instrument - are necessary in order to define the instrument. They are also suitable to this purpose because they imply constructional features of the instrument itself. In particular, the fact that the cartridge has a plurality of surgical fasteners arranged in a plurality of lines implies that the mating fastener-forming surface (136D) has also two lines to receive them; the fact that the fasteners are slidably mounted on the cartridge implies a correspondent mechanisms on the instrument (feature b) i)); the means (129) for ejecting the surgical fasteners from the cartridge assembly belong on the other hand clearly to the instrument and not to the cartridge (feature b) iv)).

4. *Novelty*

Novelty is not an issue in this case, having been not objected to by the appellant.

5. *Inventive step*

5.1 The nearest state of the art is uncontestedly document D5. It discloses a surgical apparatus for driving surgical fasteners into body tissue for adjoining two hollow organs comprising a frame and a portion defining a longitudinal axis and extending distally from said frame, said portion including:

- i) an elongate housing (1) having a distal member for mounting a cartridge assembly (3), said cartridge assembly including a plurality of surgical fasteners slidably mounted therein arranged in a plurality of lines, and having a tissue-engaging surface;
- ii) an anvil member (23) having a proximal end and a fastener-forming surface (9), said proximal end mounted to said elongate housing such that the anvil member is movable between an open position and a closed position;
- iii) means (12, 24, 25, 26) for moving said anvil member between said open position and said closed position which, by distal movement moves the anvil member to its closed position and clamps tissue between the anvil member and the cartridge assembly;
- iv) independent means (31, 10, 6, 32) for ejecting said surgical fasteners from said cartridge assembly after having clamped said tissue; whereby all of said plurality of fasteners engage said fastener-forming surface in one actuation of said ejecting means.

The subject-matter of claim 1 differs therefrom in that it comprises:

- 1) an endoscopic portion defining a longitudinal axis and extending distally from said frame;
- 2) a longitudinal center groove (136F) in the anvil member (23) to permit passage of a knife;
- 3) a plurality of fasteners-forming depressions in the fastener-forming surface of the anvil member arranged in a plurality of lines and in close co-operative alignment with the tissue-engaging surface of the cartridge assembly;
- 4) and in that the anvil member is pivotally mounted relative to the elongate housing proximally of its fastener-forming surface (136D). (In contrast thereto, the anvil member of the device of document D5 is connected with the anvil through a system of pins (24, 25) slidable in cam slots (26).);
- 5) the endoscopic portion (103) having a gripping ring (424) or thumb wheel (123) at its proximal end for rotating the endoscopic portion around the longitudinal axis and relative to the frame (102).

5.2 According to D5, page 3, last paragraph, the known stapling device is intended to be introduced into narrow and deep wounds. This means it is constructed to be used in open surgery, where the operational field is accessible to both hands of the surgeon, for easy positioning of the organ to be sutured relative to the stapling device. As soon as endoscopic surgery made its way, there arose the need for a stapling instrument, which could perform the same functions under the restricted conditions of this type of surgery: no direct manual and visual access to the operational site.

The subject-matter of claim 1 solves the problem to meet this need of the endoscopic practitioner.

Endoscopic instruments are characterized by having operating tools which can be inserted in small entrance wounds in the body and can operate in body areas which are out of direct reach of the surgeon's eyes and hands. Surgical anastomosis is a connection created between two normally separated spaces or organs. In surgical anastomosis is essential to achieve a proper instrument positioning before actuating the fastening mechanism. This may require multiple attempts to clamp the tissue prior to firing the instrument (see column 23 of the description, from line 40). Furthermore, it is desirable that after insertion the endoscopic portion of the instrument may be rotated in order to appropriately orient the instrument at the stapling site (see column 23 of the description, from line 2). The solution provided by the invention, consisting of a gripping ring or a thumb wheel at the proximal end for rotating the endoscopic portion relative to the frame, gives the surgeon increased flexibility in the operations, allowing a finely tuned orientation of the endoscopic portion independently from the orientation of the frame by means of merely two fingers (gripping ring) or the thumb.

- 5.3 The person skilled in the art would not arrive in an obvious way to the invention even with the consideration of the teaching of documents D8 to D11. The device according to document D8 is a surgical stapling instrument for forming and implanting a staple in the skin or fascia of a patient to close a wound or incision therein. The instrument presents two resilient bushings (59, 60) on the frame which allow the nose portion of the instrument to rotate in the handle portion while being held in position. The instrument is not suitable for endoscopic anastomosis. Document D9

discloses a similar mechanism (see Figure 3, reference numbers 148 and 154, Figure 4, reference number 248), but without the possibility to fix the angular position of the distal part. The purpose of that mechanism is similar to that the invention, that is to allow the surgeon to hold with his hand the instrument, with ease and absence of fatigue, and still have the possibility to change the presentation of the clips to a surgical site (see description, column 1, from line 24, and from line 59; column 2, from line 40). However, this instrument is equally not suitable for surgical anastomosis; in particular, it is designed to fire only one clip at a time. Document D10 concerns a surgical stapler device having a cylindrical portion 22 which provides a controllable orientation of the angular position of the barrel (distal portion of the instrument). Document D11 relates to a surgical fastener where the fastener applying assembly is perpendicular to a rotatable shaft assembly, which is connected to a proximal actuator assembly. Both last devices are not suitable for endoscopic anastomosis either. None of the devices according to the documents D8 to D11 discloses a clamping mechanism which is operable independently of the firing mechanism; therefore they are not suitable for a fine rotational adjustment after clamping.

The further distinguishing features of claim 1 with respect to document D5 are also directed to improve and facilitate operations by endoscopic anastomosis. The longitudinal center groove and the fastener-forming depressions in the anvil member improve accuracy in the relative position of the incision and the two sutures. The pivotal rotation of the anvil instead of the composite movement of document D4 improves clamping

accuracy and it appears more suitable to endoscopic surgery.

Accordingly, the subject-matter of claim 1 involves an inventive step.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the first instance with the order to maintain the patent in amended form on the basis of claims 1 to 19 and pages 1 to 4 of the description, as submitted during the oral proceedings; rest of the description and figures as granted.

The Registrar:

The Chairman:

V. Commare

W. D. Weiß