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**Datasheet for the decision
of 20 October 2022**

Case Number: T 0163/16 - 3.2.02

Application Number: 08001812.0

Publication Number: 1915955

IPC: A61B17/072

Language of the proceedings: EN

Title of invention:

Surgical stapler with universal articulation and tissue pre-clamp

Patent Proprietor:

Covidien LP

Opponent:

ETHICON ENDO-SURGERY, INC.

Headword:

Relevant legal provisions:

EPC Art. 54, 56, 83, 100(a), 100(b)

Keyword:

Sufficiency of disclosure - (yes)

Novelty - (yes)

Inventive step - (yes)

Decisions cited:

T 0515/00

Catchword:



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Case Number: T 0163/16 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 20 October 2022

Appellant: Covidien LP
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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 17 November
2015 revoking European patent No. 1915955
pursuant to Article 101(3)(b) EPC**

Composition of the Board:

Chairman M. Alvazzi Delfrate
Members: D. Ceccarelli
C. Schmidt

Summary of Facts and Submissions

I. The patent proprietor appealed against the Opposition Division's decision to revoke the patent.

II. Oral proceedings took place on 20 October 2022.

III. The appellant requested that the decision under appeal be set aside and that the patent be maintained as granted (main request) or, in the alternative, on the basis of one of auxiliary requests 1 to 3, filed on 14 March 2016, or on the basis of auxiliary request 4, filed by letter dated 27 March 2017.

IV. The respondent requested that the appeal be dismissed.

V. The following documents are relevant to this decision:

E1: US 2002/0143346 A1

E4: US 5,485,952 A

E5: EP 0 741 996 A2

E6: US 5,312,023 A

VI. Claim 1 of the patent as granted reads as follows:

"A tool assembly (100) comprising:

an anvil assembly (110) and a cartridge assembly (200), the cartridge assembly (200) having a plurality of staples and being movable in relation to the anvil assembly (110) between an open position and an approximated position, the cartridge assembly (200) and the anvil assembly (110) defining a tissue gap in the approximated position, the anvil assembly (110) having a slot (112) extending from a proximal end of the anvil

assembly (110) to a distal end of the anvil, the slot (112) having a depending portion and a transverse upper portion;
a clamp collar (140) positioned adjacent the proximal end of the cartridge assembly (200) and the anvil assembly (110) and being movable from a first position to a second position to effect movement of the anvil assembly (110) in relation to the cartridge assembly (200) from the open position towards the approximated position; and
a dynamic clamping member (150) movably positioned in relation to the anvil assembly (110) and the cartridge assembly (200), the dynamic clamping member (150) being movable from a first position to a second position and a first mechanical interface (159) of the dynamic clamping member (150) being longitudinally reciprocatable within the upper portion of the slot (112) in the anvil assembly (200), the upper portion of the slot (112) being dimensioned to slidably receive the first mechanical interface (159)
wherein the dynamic clamping member (150) includes a second mechanical interface (152) which slidably engages the cartridge assembly (200), the first and second mechanical interfaces (159, 152) of the dynamic clamping member (150) being in substantial vertical registration relative to one another to oppose expansive forces associated with clamping and stapling tissue."

Claims 2 to 6 are dependent claims.

VII. The appellant's argument relevant to the decision can be summarised as follows.

Sufficiency of disclosure

The person skilled in the art would not consider that claim 1 of the patent as granted encompassed hypothetical embodiments in which the dynamic clamping member was moved before or at the same time as the clamp collar. Claim 1 stated that the dynamic clamping member slidably engaged the anvil slot and the cartridge assembly "to oppose expansive forces associated with clamping and stapling tissue". The dynamic clamping member could only oppose expansive forces associated with stapling tissue when the cartridge assembly and the anvil assembly were in the approximated position, i.e. after the clamping collar had moved the anvil assembly and the cartridge assembly between the open and approximated positions. Hence according to the claim, the clamping collar was used to pre-clamp the anvil assembly and the cartridge assembly prior to movement of the dynamic clamping member. This was supported by the disclosure as a whole.

Moreover, an invention could not be considered to be irreproducible merely because a claim encompassed hypothetical embodiments laying outside the breadth of the claim (T 515/00).

Novelty in view of E1

E1 did not disclose a clamp collar being movable to effect movement of an anvil assembly from an open position towards an approximated position within the meaning of claim 1 of the patent as granted.

Both the patent and E1 defined three different states of the anvil assembly with respect to a cartridge assembly: an open state in which the insertion and the grasping of tissue between the assemblies were possible, an approximated pre-clamping state with a defined tissue gap, and a final fully clamped state.

In E1 a cable could effect a gross approximation between the open and the approximated position. A clamp collar (60 in Figure 18) could be used to perform a fine approximation of the assemblies from the approximated pre-clamping state to the fully clamped position (paragraph [0040]). There was no disclosure that the clamp collar could effect the gross approximation.

Inventive step

The subject-matter of claim 1 of the patent as granted was inventive in view of the combination of E1 with E4, E5 or E6 and over the combination of E4 with E1.

Starting from E1, the distinguishing feature of the clamp collar being movable to effect movement of an anvil assembly from an open position towards an approximated position permitted to achieve approximation acting on the proximal side of the tool assembly. The cable of E1 achieved approximation from the distal side.

This technical effect solved to problem of increasing the maneuverability of the tool assembly.

None of E4, E5 or E6 disclosed a tool assembly with a two-stage approximation, i.e. a gross approximation from an open to an approximated state and a fine

approximation from the approximated to the fully clamped state as in the patent and in E1. Hence, these documents did not teach a clamp collar to effect movement of an anvil assembly from an open position towards an approximated position as defined in claim 1 of the patent as granted.

Starting from E4, this document did not disclose a dynamic clamping member as defined in claim 1 of the patent as granted. According to E4 a clamp collar was used to perform approximation of an anvil assembly and a cartridge assembly in a single step.

The distinguishing feature permitted to effectively drive out fluid from tissue already pre-clamped between the anvil and the cartridge assembly. Hence, it solved the objective technical problem of achieving more precise cutting and stapling.

E1 taught an I-beam or a collar for performing fine approximation of the cartridge and the anvil assemblies after a first gross approximation performed by actuation of a cable. E1 related to the specific field of performing localized resections of gastro-esophageal lesions and did not address the objective technical problem. Although the I-beam according to E1 was structurally similar to the dynamic clamping member as claimed, according to that document both the I-beam and the collar performed a final clamping function, as did the collar disclosed in E4. Hence, the person skilled in the art received no teaching to implement an intermediate approximation step and then provide the device of E4 with a dynamic clamping member in addition to the clamp collar for solving the objective technical problem.

It followed that the subject-matter of claim 1 of the patent as granted involved an inventive step.

VIII. The respondent's argument relevant to the decision can be summarised as follows.

Sufficiency of disclosure

Claim 1 of the patent as granted had no requirements regarding the structural and functional interactions between the clamp collar and the dynamic clamping member. It encompassed embodiments in which the dynamic clamping member slid before, or simultaneously with, the clamp collar from the first position to the second position. There was no disclosure of such embodiments in the patent. Hence, the person skilled in the art could not put the invention into practice over the whole scope of the claim.

Novelty in view of E1

E1 deprived the subject-matter of claim 1 of the patent as granted of novelty.

In particular, E1 disclosed a clamp collar 60 (Figure 5) positioned adjacent the proximal end of a cartridge assembly 40 and an anvil assembly 50 and being movable from a first position to a second position to effect movement of the anvil assembly 50 in relation to the cartridge assembly 40 from an open position towards an approximated position (paragraphs [0036] and [0040]).

The claim did not require the open position to be a fully open position of the anvil assembly and the cartridge assembly. The claim did not mention any

tissue gap or the ability to grasp tissue of the assemblies in an open position either. The patent defined the open position merely as a position in which a spaced relation existed between the anvil assembly and the cartridge assembly (column 8, lines 26 to 32). What the claim required was merely the suitability of the clamp collar for moving the anvil assembly and the cartridge assembly from any more open to any more closed position. The separated position between the anvil assembly 50 and the cartridge assembly 40 in Figures 15 and 18 of E1 allowed to grasp tissue and was an open position within the meaning of claim 1 of the patent as granted.

Furthermore, the clamp collar disclosed in E1 comprised a series of features which made it suitable even for moving the anvil assembly and the cartridge assembly from a fully open position to a fully closed position. Figure 18 and paragraph [0040] disclosed curved sections of an upper beam 114a and a lower beam 114b which could impinge upon respective parts of the anvil assembly and the cartridge assembly when these assemblies were at an angle corresponding to the fully open position.

Inventive step

The subject-matter of claim 1 of the patent as granted was not inventive in view of the combination of E1 with E4, E5 or E6.

A clamp collar positioned adjacent the proximal end of the cartridge assembly and the anvil assembly, and being moveable from a first position to a second position to effect movement of the anvil assembly in relation to the cartridge assembly from the open

position towards the approximated position, was equivalent to the actuation cable of E1. The technical problem solved by the clamp collar as claimed was to provide an alternative gross approximation mechanism. The problem put forward by the appellant, which related to the maneuverability of the tool assembly, could at most be derived from the absence of an actuation cable. However, the claim did not exclude the presence of such a cable. Hence, this problem was not solved by the distinguishing feature over the whole scope of the claim and was, for this reason, not correct.

In any case, the use of a clamp collar to achieve gross approximation of the cartridge assembly and the anvil assembly without preventing the advance of the assemblies over the tissue was routine in surgical stapler design, as shown for example in E4 (collar tube 90), E5 (closure tube 38, as described in particular in column 7, lines 17 to 21) and E6 (collar 400).

The subject-matter of claim 1 of the patent as granted was not inventive in view of the combination of E4 with E1 either.

Starting from E4, this document did not disclose a dynamic clamping member as defined in claim 1 of the patent as granted.

The problem solved by the dynamic clamping member was the provision of a surgical instrument comprising a means to oppose expansive forces associated with clamping and stapling tissue and to maintain a substantially uniform gap between the anvil assembly and the cartridge assembly.

E1 disclosed a first mechanism for gross approximation of the anvil assembly and the cartridge assembly and a second mechanism for fine adjustment of the assemblies relative to one another. This second mechanism could include an I-beam member (claim 13 and paragraph [0036] of E1) which also served as staple pusher (claim 14 of E1). The person skilled in the art would have readily understood, without the need of any explicit disclosure, that the I-beam member of E1 opposed expansive forces associated with clamping and stapling tissue. The I-beam member of E1 was structurally identical to the dynamic clamping member disclosed in the patent.

Thus, starting from E4, the person skilled in art would have retained the clamp member disclosed in E4 (collar tube 90) as a gross approximation mechanism and would have provided the device of E4 with the the I-beam according to E1 to obtain a fine approximation mechanism. Whether E1 and E4 described surgical instruments with different uses was of little relevance, as claim 1 of the patent as granted was broad in that respect.

It was also irrelevant that according to E4 a clamp collar was used to perform approximation of an anvil assembly and a cartridge assembly in a single step. The driving out of fluid from tissue (i.e. dewatering) started to occur when tissue was initially clamped, and continued afterwards. It was inherent in the clamping process that the clamped anvil assembly and cartridge assembly reached an intermediate position before dewatering was complete. The I-beam of E1 simply accelerated the dewatering process.

Reasons for the Decision

1. The invention

The invention relates to a tool assembly which is typically present in surgical staplers used in laparoscopic or endoscopic procedures for stapling together and then splitting tissue. Figures 1A, 1B, 4 and 13 of the patent, reproduced below, illustrate a tool assembly according to the invention.

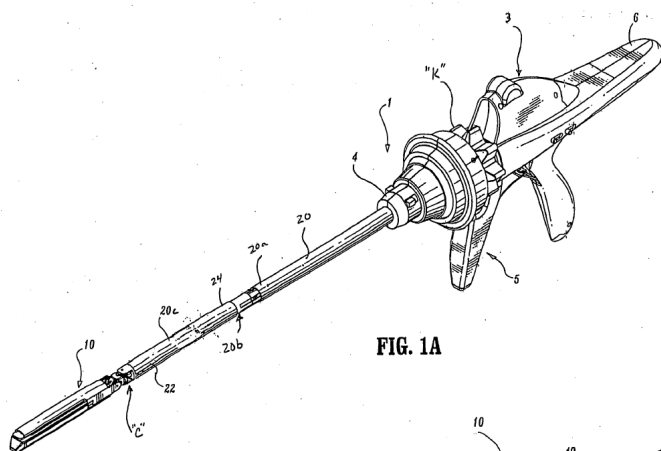


FIG. 1A

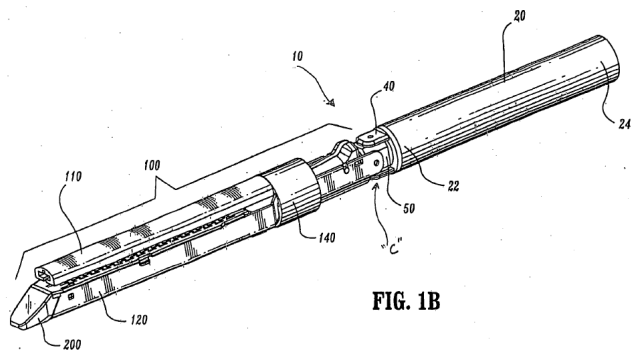


FIG. 1B

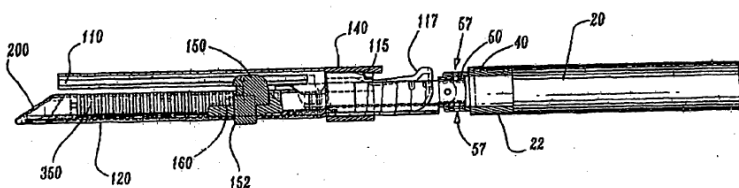


FIG. 4

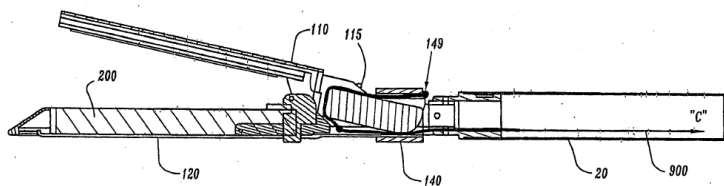


FIG. 13

The tool assembly (100) comprises an anvil assembly (110) and a cartridge assembly (200) with a plurality of staples.

As explained in the description, the tissue to be treated can first be clamped between the anvil assembly and the cartridge assembly by moving the assemblies from an open to an approximated position and then cut through along a longitudinal direction of those two components. At the same time as the tissue is cut, two rows of staples can be applied at each side of the cut.

The claimed invention also features a clamp collar (140) to move the anvil assembly and the cartridge assembly from the open position to the approximated position, and a dynamic clamping member (150) for engaging the anvil assembly and the cartridge assembly to oppose the expansive forces associated with clamping and stapling tissue.

2. Sufficiency of disclosure

The respondent, while not disputing that it was possible to carry out the invention according to the specific embodiments described in the description, submitted that the subject-matter of claim 1 of the patent as granted was not sufficiently disclosed, because it encompassed also non-described embodiments in which the dynamic clamping member could be moved before the clamp collar.

The Board does not accept this argument.

2.1 First, claim 1 of the patent in suit does not recite that the dynamic clamping member could be moved before the clamp collar. Moreover, as the appellant argued,

the claim itself states that the anvil assembly and the cartridge assembly are approximated by the clamp collar, and that the dynamic clamping member slidingly engages the anvil slot and the cartridge assembly "to oppose expansive forces associated with clamping and stapling tissue".

Since such expansive forces are a consequence of the approximation, it is at least questionable that the non-described embodiments referred to by the respondent fall within the scope of the claim.

- 2.2 In any case, Article 83 EPC requires that the invention must be disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. In view of this article, it is not problematic that claims - as is typically the case - represent a generalisation of the teaching of the description and the drawings.

Decision G 1/03, point 2.5.2, further establishes that a claim might encompass non-working embodiments and still be allowable as long as the specification "contains sufficient information on the relevant criteria for finding appropriate alternatives over the claimed range with a reasonable effort". Point 2.5.2 of G 1/03 refers in particular to the case law represented by, for instance, T 301/87, according to which "it is not necessary for the purpose of Articles 83 and 100(b) EPC that the disclosure of a patent is adequate to enable the skilled man to carry out all conceivable ways of operating the invention which are embraced by the claims" (point 3.2). T 515/00, cited by the appellant, comes to the same conclusion.

2.3 In the current case, the patent discloses how to put into practice a tool assembly with a clamp collar and a dynamic clamping member in accordance with claim 1 and, for example, paragraphs [0026], [0033] and [0034] and Figures 11B and 13.

In respect of the movement of the dynamic clamping member and the clamp collar addressed by the respondent, the patent as a whole explains the advantages of performing gross approximation of the anvil assembly and the cartridge assembly, using the clamp collar, and fine approximation via the dynamic clamping member, to oppose expansive forces associated with clamping and stapling tissue (paragraphs [0027] and [0030]). Since the tissue is stapled only after the anvil assembly and the cartridge assembly have been approximated, the person skilled in the art is consistently taught to carry out the invention with the clamp collar arranged to move and perform gross approximation before the dynamic clamping member is moved. In view of this teaching, which allows achieving the advantages explained in the patent, the person skilled in the art can put into practice the invention as defined in claim 1.

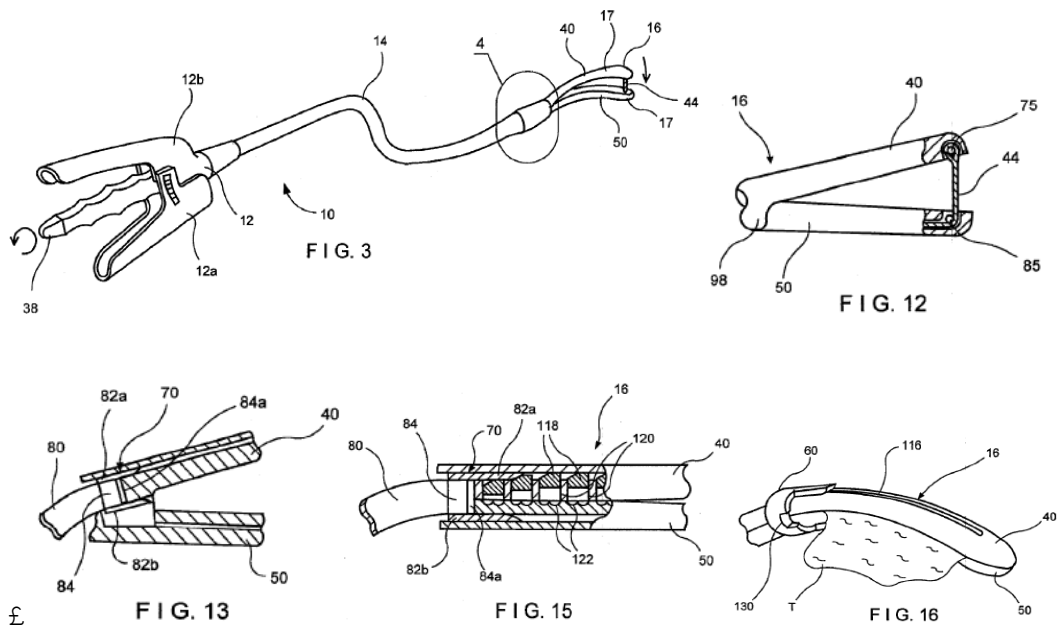
It follows that the ground for opposition of insufficiency of disclosure (Article 100(b) EPC) raised by the respondent does not prejudice the maintenance of the patent as granted.

3. Novelty in view of E1

The respondent argued that E1 deprived the subject-matter of claim 1 of novelty.

E1 discloses a surgical stapler with an actuation

mechanism for performing gross approximation of a pair of jaws (see Figures 3, 12, 13, 15 and 16 reproduced below and paragraph [0035], second and third sentence).



According to E1, which is specifically related to the treatment of gastro-esophageal lesions (paragraph [0001] and Figures 1, 2c, 11, 21 and 22), the actuation mechanism for performing gross approximation is in the form of a cable 44 at the distal end of the stapler. According to one embodiment, the surgical stapler comprises a clamping member (60) in the form of a clamp collar for performing fine approximation of the jaws (paragraph [0036]).

E1 does not directly and unambiguously disclose a clamp collar to effect movement of an anvil assembly in relation to a cartridge assembly from an open position towards an approximated position as defined in claim 1.

E1 expressly states that clamping member 60 is actuated to "finely approximate the jaws" (paragraph [0036]). This is done after the jaws are grossly approximated

(paragraph [0035], first sentence).

Only the gross approximation - not the fine approximation - can be considered the movement from an open position to an approximated position as defined in claim 1: the position of the jaws after the gross approximation is not an "open" position in the technical context of a surgical stapler. The appellant's argument that any position with a spaced relation between an anvil assembly and a cartridge assembly of the surgical stapler qualified as an "open" position within the meaning of claim 1 is not persuasive, as it is based on a merely literal interpretation of the claim wording. For the person skilled in the art, a surgical stapler in an open position must allow the surgeon to readily introduce tissue between its jaws. The description of the patent is consistent with this interpretation. According to column 8, lines 26 to 32 referred to by the respondent, moving the anvil assembly and the cartridge assembly into the grossly approximated position will cause the assemblies to grasp tissue. This means that in the grossly approximated position, the surgeon cannot introduce any more tissue between the assemblies.

The respondent's argument that the clamp collar disclosed in E1 was inherently suitable for moving the jaws from a fully open to a fully closed position is not convincing either. E1 is silent in this respect. The curved sections of upper beam 114a and lower beam 114b referred to by the appellant and depicted in Figures 15 and 18 do not directly and unambiguously provide this suitability either, as the latter depends also on the non-disclosed configuration of the jaws in the open position in relation to the clamp collar. Figure 13, which discloses open jaws in relation to an

I-beam 70 used to perform fine approximation, shows that the I-beam is not suitable for moving the jaws from the open to the closed position, in spite of the fact that the I-beam has curved sections similar to those of clamp collar 60.

It follows that the subject-matter of claim 1 of the patent as granted is novel over E1.

Hence, the ground for opposition of lack of novelty (Article 100(a) EPC and Article 54 EPC) raised by the respondent does not prejudice the maintenance of the patent as granted.

4. Inventive step

4.1 The respondent argued that the subject-matter of claim 1 of the patent as granted was not inventive in view of the combination of E1 with E4, E5 or E6.

As established above, E1 does not disclose that the clamp collar is suitable for effecting movement of the anvil assembly in relation to the cartridge assembly from the open position towards the approximated position.

According to E1, this movement is performed by the actuation of cable 44.

The possibility of using the clamp collar, which inherently acts on the proximal side of the tool assembly, for moving the anvil assembly and the cartridge assembly into the approximated position instead of a cable at the distal side of the tool assembly has the technical effect that in the open position tissue can be inserted between the cartridge

assembly and the tool assembly from the distal side of the tool without hindrance.

This solves the objective technical problem of facilitating the manipulation of tissue.

The problem put forward by the respondent, i.e. the provision of an alternative mechanism for gross approximation, is not accepted, since it does not take into account the technical effect produced by the distinguishing feature. The respondent's argument that claim 1 of the patent as granted did not exclude the presence of an actuation cable is not convincing. This argument is based on a merely literal and theoretical interpretation of the claim wording. The fact that the presence of an actuation cable is not expressly disclaimed does not mean that the claim must encompass embodiments comprising an actuation cable as in E1. It is questionable whether the presence of both a clamp collar as claimed and an actuation cable as in E1 would be technically meaningful at all. Moreover, the mere possibility of doing away with the actuation cable without losing the functionality of the gross approximation already addresses the objective technical problem.

It is common ground that each of E4, E5 and E6 discloses a clamp collar for effecting movement of an anvil assembly and a cartridge assembly from an open position towards an approximated position.

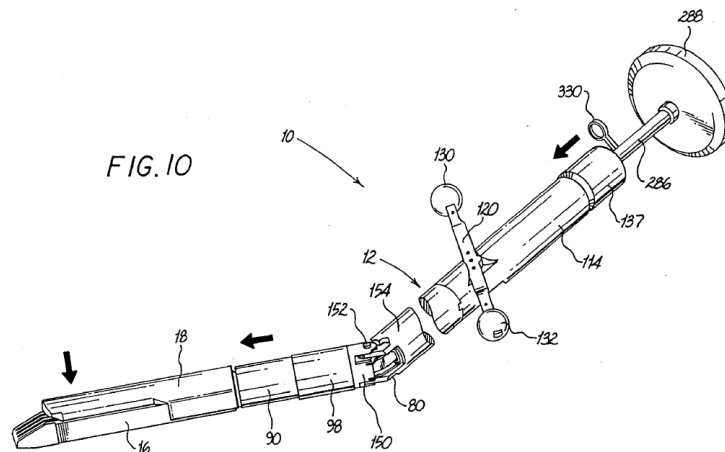
However, none of E4 to E6 disclose a mechanism for performing gross approximation first, followed by fine approximation, like the one disclosed in E1. It is common ground that the clamp collars disclosed in E4 to E6 are used to perform a one-step approximation.

The person skilled in the art would have received no teaching to replace an element of the two-step approximation mechanism of E1 from documents which do not disclose such a mechanism and do not address the objective technical problem in this respect. The person skilled in the art could have simply replaced the whole mechanism of E1 with a mechanism according to one of E4 to E6 in view of the objective technical problem.

Hence, starting from E1 in combination with any of E4 to E6 the subject-matter of claim 1 of the patent as granted, which stipulates a two-step approximation mechanism, would not have been arrived at in an obvious way.

4.2 The respondent also argued that the subject-matter of claim 1 of the patent as granted was not inventive in view of the combination of E4 with E1.

E4 concerns a surgical stapler as depicted in Figure 10, reproduced below.



The surgical stapler comprises a proximal portion (12) and an articulating portion (14) to which a cartridge housing (16) and an anvil member 18 are connected. By

actuating a handle clamp (137) collar tube (90) causes the approximation of the anvil member and the cartridge housing (column 8, line 61 to column 9, line 4). Collar tube 90 is a clamp collar within the meaning of claim 1 of the patent as granted. However, collar tube 90 is the only mechanism for performing approximation of the anvil assembly and the cartridge assembly.

It is common ground that E4 does not disclose a dynamic clamping member as defined in the claim.

The dynamic clamping member has the technical effect recited in the claim of opposing expansive forces associated with clamping and stapling tissue.

This addresses the objective technical problem of providing a more accurate and stable stapling mechanism, as the appellant submitted.

The problem put forward by the respondent is not acceptable as it comprises elements of the claimed solution.

It is true that E1 discloses a first mechanism for gross approximation of the anvil assembly and the cartridge assembly and a second mechanism for fine adjustment of the assemblies in the form of an I-beam member (claim 13 and paragraph [0036] of E1) structurally similar to the dynamic clamping member defined in claim 1 of the patent as granted.

However, E1 teaches a specific tool assembly for gastro-esophageal lesions. Cable 44 disclosed in E1 is of no hindrance for the specific field of application of E1, but would make the assembly of E4, directed also to the treatment of blood vessels, useless because it

would hinder the introduction of tissue from the distal side of the assembly. Moreover, the mechanical design of the clamping mechanism of E4 would make it difficult to implement only the I-beam of the approximation mechanism disclosed in E1. E1 does not disclose a clamp collar for performing gross approximation. Finally, there is no teaching in E1 on the objective technical problem or even on the need of quickly driving out fluid from the clamped tissue (dewatering) mentioned by the respondent.

Hence, the subject-matter of claim 1 of the patent as granted is not obvious in view of the combination of E4 with E1.

- 4.3 It follows that the ground for opposition of lack of inventive step (Article 100(a) EPC and Article 56 EPC) raised by the respondent does not prejudice the maintenance of the patent as granted.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The patent is maintained as granted.

The Registrar:

The Chairman:



A. Chavinier-Tomsic

M. Alvazzi Delfrate

Decision electronically authenticated