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

Case Number: T 0717/15 - 3.2.02

Application Number: 10006455.9

Publication Number: 2233082

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. 56, 76(1), 100(a), 100(c), 123(2)
RPBA Art. 12(4)

Keyword:

Objections examined by the opposition division -
admitted (yes)
Added subject-matter (no)
Inventive step - (yes)

Decisions cited:

Catchword:



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Case Number: T 0717/15 - 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 3 March 2015
revoking European patent No. 2233082 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.

The patent is derived from a divisional application of European patent application No. 08 001 812.0, which is itself a divisional of European patent application No. 06 013 920.1, which is itself a divisional of European patent application No. 03 774 605.4 ("the first parent application").

- II. Oral proceedings took place on 20 October 2022.

The appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request filed with a letter dated 8 April 2015 or, in the alternative, one of auxiliary requests 1 and 2 filed with the letter dated 8 April 2015 and auxiliary request 3 filed with a letter dated 20 June 2017.

The respondent requested that the appeal be dismissed.

- III. The following documents are relevant to this decision:

D1: US 5,456,401 A
D2: US 5,692,668 A
D3: US 5,485,952 A
D4: US 2002/0143346 A1
D5: US 5,507,426 A
D9: US 5,465,895 A
D10: US 5,807,393 A
D11: US 5,814,055 A

IV. Claim 1 of the main request reads as follows:

"A surgical stapler, comprising:

a tool assembly (100) including a cartridge assembly (200) having a plurality of staples and an anvil assembly (110), the anvil assembly and the cartridge assembly having an open position and an approximated position;

a dynamic clamping member (150) having an upper camming surface (159) which engages the anvil assembly and a lower camming surface which engages the cartridge assembly, wherein the upper and lower camming surfaces are configured to oppose the expansive forces associated with clamping and stapling tissue and to maintain a substantially uniform gap between the anvil assembly and the cartridge assembly during stapling;

a sled (160) translatable through the cartridge assembly with the dynamic clamping member; the sled having at least one angled surface thereon, said sled being movable along the cartridge assembly such that at least one angled surface of said sled forces said plurality of staples to deform against a bottom surface of the anvil assembly;

a pre-clamping collar (140) positioned adjacent the proximal end of the cartridge assembly and the anvil assembly and being movable to bias against a cam surface on the anvil to move the anvil assembly and cartridge assembly between the open position and approximated position; and

a pivot block (50) attached to the tool assembly and attached to an elongate shaft (20) for pivoting the tool assembly about a Z axis and a Y axis perpendicular to an X axis defined by the elongate shaft."

Claims 2 to 8 are dependent claims.

- V. The appellant's arguments relevant to the decision can be summarised as follows.

Extension of subject-matter

The objections of added subject-matter against the main request should not be admitted into the appeal proceedings. The main request corresponded to the first auxiliary request in the first-instance proceedings. According to the impugned decision and the minutes of the oral proceedings before the Opposition Division, the opponent had no objections of added subject-matter against that request. Objections raised for the first time on appeal should be held inadmissible under Article 12(4) RPBA 2007 as they could and should have been raised during the first-instance proceedings. In any event, claim 1 of the main request did not include added subject-matter.

The respondent's objection on the omission in claim 1 of the main request of the tubular connector was without merit. The first parent application as filed (Figure 1) disclosed a tool assembly having a tubular connector removably attached to the distal end of a shaft extending from a stapler housing. The tubular connector was connected at its distal end to the tool assembly through a pivotable connector mechanism "C", which was the pivot block according to claim 1 of the main request. However, the person skilled in the art was taught that the tool assembly could also be connected directly to the shaft. In relation to Figure 1, page 11, lines 4 to 7 disclosed that the tool assembly could be "pivotally, operatively, integrally attached, for example, through a connection mechanism such as C permanently and directly to distal end 20a of shaft 20 of a disposable surgical stapler".

Accordingly, no tubular connector intermediate to the tool assembly and the shaft was needed.

The omission of a channel assembly in claim 1 of the main request was allowable. The summary of the invention stated that "preferably, the tool assembly also includes an anvil having a bottom surface and a channel assembly to support the staple cartridge therein". The use of the word "preferably" showed that the channel assembly was not essential. The embodiment of Figure 1, referred to by the respondent, was specific and non-limiting.

Independent claims 1 and 19 of the first parent application as filed were directed to tool assemblies suitable for use in staplers according to the invention as defined in claim 1 of the main request. None of these claims of the first parent application as filed required the camming surfaces of the dynamic clamping member to be located in slots in the cartridge assembly or the anvil assembly. Slots were mentioned in dependent claims 2 and 3, confirming that they were a preferred, not essential, feature. The same conclusion was reached considering the corresponding passages in the summary of the invention in the first parent application as filed. The term "configured" was equivalent to the term "arranged" as they both defined functional limitations on sizes, shapes and materials.

Claim 1 of the main request was based on a combination of claims 9, 11 and 12 of the first parent application as filed. None of these claims had the feature that the upper and lower camming surfaces were in substantially vertical registration. This feature, which was only included in dependent claim 13, was not essential and did not need to be included in claim 1.

Inventive step

The subject-matter of claim 1 of the main request was inventive when starting from D1, D2 or D3 in combination with D4 or D5.

D1 to D3 did not disclose a dynamic clamping member.

An advantage of the claimed invention was that the stapler was provided with two different clamping mechanisms in the form of a pre-clamping collar and a dynamic clamping member. The pre-clamping collar provided a pre-clamp stage in which the anvil assembly and the cartridge assembly were approximated and tissue was pre-squeezed between the assemblies. During subsequent and further clamping by means of the dynamic clamping member as the stapling proceeded, there was less fluid flow in the tissue in the area of further clamping. This enhanced tissue stabilisation and compression as well as the accuracy of stapling.

Accordingly, the objective technical problem starting from D1, D2 or D3 was to provide a stapler with a more accurate and stable stapling mechanism.

D4 disclosed an actuation cable for gross approximation of the jaws of a stapler (Figures 12 to 15 and paragraph [0035]). It also disclosed an I-beam member 70 which would function as a dynamic clamping member. However, there was no indication in D4 that the I-beam member improved the accuracy of the stapling process. D4 did not discuss the problem of staple displacement or the need to pre-clamp tissue to reduce fluid flow during stapling, let alone that the I-beam member 70 could play a role in addressing this problem.

Moreover, the actuation cable of D4 was not functionally equivalent to the clamping collar of D1, D2 or D3. The actuation cable of D4 was at the distal end of the stapler, whereas the clamping collar of D1, D2 or D3 was at the proximal end of the jaws of the device. At best, if the person skilled in the art had sought to combine D1, D2 or D3 with D4 to provide a two-step clamping process, they would have combined the proximal collar type mechanism of D1, D2 or D3 with the distal actuation cable of D4.

The gist of D5 was to provide a stapler with a dynamic clamping member that could effect progressive closure of the anvil and concomitantly effect sequential ejection of staples from the cartridge. D5 taught to provide a dynamic clamping member that closed the jaws of the stapler and ejected staples in a single action. This was completely different from the gist of the invention as defined in claim 1 of the main request, which was to effect pre-clamping with the pre-clamping collar followed by advancing the dynamic clamping member only during ejection of the staples. The person skilled in the art might have considered replacing the various pre-clamping mechanisms of D1 to D3 with the dynamic clamping member of D5, but this would have directly contradicted the gist of D5 to use the dynamic clamping member of D5 in addition to those mechanisms. Moreover, it would have been technically complicated to combine the dynamic clamping member of D5 with the mechanisms disclosed in D1 to D3.

The subject-matter of claim 1 of the main request was also inventive over the combination of D4 with any of D1 to D3.

D4 did not disclose a pre-clamping collar positioned

adjacent to the proximal end of the cartridge assembly and the anvil assembly that was movable to move the anvil assembly and the cartridge assembly between the open position and the approximated position. It taught to pre-clamp tissue in the jaws of a stapler by means of an actuation cable 44 at the distal end of the jaws. This was completely different from the use of a pre-clamping collar as defined in claim 1 of the main request. Therefore, both the construction and the modus operandi of the stapler of D4 were fundamentally different from the claimed invention. Hence, D4 was not a suitable starting point towards the claimed invention.

The prior art did not suggest that the technical problem of effectively clamping tissue and maintaining a constant tissue thickness during stapling could be solved by the combination of a pre-clamping collar and a dynamic clamping member as defined in claim 1 of the main request.

VI. The respondent's arguments relevant to the decision can be summarised as follows.

Extension of subject-matter

The objections of added subject-matter against the main request should be admitted into the appeal proceedings. The main request corresponded to the first auxiliary request in the first-instance proceedings. The respondent had stated in the oral proceedings before the Opposition Division that it did not have any objections of added subject-matter specifically directed to that first auxiliary request. However, objections of added subject-matter against features of claim 1 of the main request in the first-instance

proceedings, which were present in claim 1 of the main request on appeal, had been raised by the respondent and considered by the Opposition Division in the impugned decision. The objections of added subject-matter against the main request on appeal were maintained against those same features. Hence, these objections had to be considered in the appeal proceedings. However, the respondent withdrew its objections of added subject-matter against the dependent claims of the main request on appeal.

Claim 1 omitted a tubular connector which mounted a pivot block allowing pivotable movement of the tool assembly about a Y axis and a Z axis defined perpendicular to a longitudinal X axis. However, claim 9 of the first parent application as filed, on which claim 1 of the main request was based, comprised the definition of such a tubular connector. Moreover, page 13, first full paragraph of the first parent application as filed disclosed a pair of opposing flanges for receiving respective pivot pins to mount the pivot block. Without these elements, claim 1 of the main request defined no relationship between the pivot block and the elongate shaft. While some passages of the first application as filed disclosed general tool assemblies attached to a general shaft, the tubular connector with its elements was the only disclosed component which enabled the pivotal movement of the pivot block as defined in claim 1. Its omission amounted to a non-allowable intermediate generalisation.

Claim 1 of the main request specified no channel assembly, whereas claim 9 of the first parent application as filed recited a channel assembly configured to support a staple cartridge. Although the

first parent application as filed disclosed (on page 5, fourth paragraph, first three lines) a tool assembly only preferably including a channel assembly, this was for an embodiment described in the preceding paragraphs in which the tool assembly was still undefined. However, claim 1 of the main request defined many features of the tool assembly, including a staple cartridge. In view of page 11, penultimate sentence and Figures 11A to 11D with their description on page 9, the first parent application as filed provided no disclosure of a tool assembly comprising a staple cartridge without a channel assembly to support it. Hence, claim 1 of the main request included added subject-matter because it omitted the channel assembly.

There was no basis for the general definition of the camming surfaces of the dynamic clamping member engaging the anvil and cartridge assemblies and configured to oppose expansive forces in claim 1 of the main request. Claim 12 of the first parent application as filed recited a first mechanical interface which translated within a corresponding slot disposed within the anvil upon movement of the sled and a second mechanical interface which translated within a corresponding slot disposed within the channel assembly upon movement of the sled. The description, in particular pages 20 and 21, was even more specific. Although page 28, paragraph 2, line 16 to page 29, paragraph 1 disclosed that the upper and lower camming means could be something other than an upper pin and a bottom flange, there was no disclosure that T-shaped slots in the anvil and cartridge assemblies, the slots receiving the sliding camming means and a central web of the dynamic clamping means could be omitted. Both the claims and description of the first parent application as filed specified the interaction of a

mechanical interface, pin or flange with a corresponding slot. This could not be extended to a general camming surface which engaged with the anvil/cartridge assembly. Without slots within which the camming means were slidably received, the gap between the anvil assembly and the cartridge assembly could not be maintained since the spacing between these assemblies would only be limited in the opening direction (last four lines of page 24 of the first parent application as filed). Moreover, the expression "configured to oppose the expansive forces associated with clamping and stapling tissue and to maintain a substantially uniform gap between the anvil assembly and the cartridge assembly during stapling" referring to the camming surfaces of the dynamic clamping member was more general than the disclosure of the first parent application as filed, according to which the camming surfaces were in a specific arrangement to obtain the claimed effect. The term "configured" encompassed but was not restricted to "arranged".

Claim 1 of the main request recited the effect of the upper and lower camming surfaces maintaining a substantially uniform gap in isolation from the vertical registration of the camming surfaces, which was required to achieve the uniform gap. The maintenance of the spacing between the anvil assembly and the cartridge assembly had only ever been disclosed as being achieved by the vertical registration of the first and second mechanical interfaces.

Inventive step

The subject-matter of claim 1 of the main request lacked an inventive step when starting from D1, D2 or D3 in combination with D4 or D5.

D1 to D3 did not disclose a dynamic clamping member having an upper camming surface which engages the anvil assembly and a lower camming surface which engages the cartridge assembly with the upper and lower camming surfaces being configured 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, as defined in claim 1 of the main request.

The objective technical problem solved by this distinguishing feature was the provision of a surgical instrument which comprised 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. This stabilised and improved the accuracy of the clamping and stapling process.

D4 disclosed a first jaw mechanism for gross adjustment of the position of the jaws relative to one another and a second jaw moving mechanism for fine adjustment of the jaws relative to one another. According to D4, the second jaw moving mechanism could include an I-beam member, with a first portion (upper beam portion 82a) of the I-beam member being received in the first jaw and a second portion (lower beam portion 82b) of the I-beam member being received in the second jaw. The I-beam member also served as a staple pusher. The skilled person would readily understand that the I-beam member opposed expansive forces associated with clamping and stapling tissue since the upper and lower I-beam portions, which were at a fixed vertical distance from one another, were configured to ride in the slots of the jaws. It was immediately apparent to

the person skilled in the art that a dynamic clamping member as disclosed in D4 would improve the accuracy of the stapling process. Furthermore, the skilled person was well acquainted with I-beam members for achieving approximation. Thus, starting from any of D1 to D3, the person skilled in the art would retain their gross approximation mechanisms and add the I-beam member from D4 to provide a fine approximation mechanism to solve the objective technical problem.

D5 disclosed (lines 33 to 45, column 4 and Figure 2) a dynamic clamping member (actuation mechanism 50) having an upper camming surface (cam plate 54) which engaged the anvil assembly and a lower camming surface (lower cam plate 56) which engaged the cartridge assembly. D5 stated (lines 40 to 46, column 4) that, in use, when actuation mechanism 50 translated, the upper cam plate 54 engaged an upper surface of an anvil member to urge it toward a cartridge and the lower cam plate 56 engaged an under surface of a floor to balance the compressive forces imparted on the anvil by the upper cam plate. The distal translation of the actuation mechanism 50 brought the upper surface of the anvil member into closer cooperative alignment with the tissue contacting surface of the cartridge, clamping the body tissue disposed between these surfaces (column 5, lines 26 to 31). Hence, D5 expressly taught that the upper and lower camming surfaces were configured to oppose the expansive forces associated with clamping and stapling tissue and to maintain a substantially uniform gap between the anvil assembly and the cartridge assembly during stapling. Thus, the person skilled in the art would add the dynamic clamping member of D5 to the device of one of D1 to D3, arriving at the claimed invention without exercising any inventive skill. There was no technical difficulty

in doing so, in particular starting from D2, since both D2 (column 4, lines 31 to 41 disclosed an articulating coupling device in the form of a ball-in-socket type coupling) and D5 disclosed articulated staplers, this implying the ability to actuate the approximation mechanisms through articulation joints.

The subject-matter of claim 1 of the main request was not inventive over the combination of D4 with any of D1 to D3 either.

D4 did not disclose a pre-clamping collar positioned adjacent to the proximal end of the cartridge assembly and the anvil assembly and being movable to move the anvil assembly and the cartridge assembly between the open position and the approximated position. D4 taught an actuation cable to achieve gross approximation of the cartridge assembly and the anvil assembly. The actuation cable of D4 was equivalent to the clamping collars disclosed in D1 to D3 because, like the clamping collar, it provided gross approximation of the cartridge assembly and the anvil assembly, resulting in clamping of tissue placed between them.

The technical problem solved by the distinguishing feature was an alternative gross approximation mechanism.

The use of a clamping collar to achieve gross approximation of the jaws was routine in surgical stapler design. D1 to D3 disclosed such a clamping collar (closure tube 400 of D1, closure sheath 32 of D2 and collar tube 90 of D3). Such a clamping collar was also disclosed in D9, D10 and D11. Hence, the provision of a pre-clamping collar was an obvious solution to the

technical problem of providing an alternative gross approximation mechanism.

Reasons for the Decision

1. The invention

The invention relates to a surgical stapler for use in laparoscopic or endoscopic procedures for stapling together and then splitting tissue. Figures 1A, 1B, 4 and 13 of the patent are reproduced below.

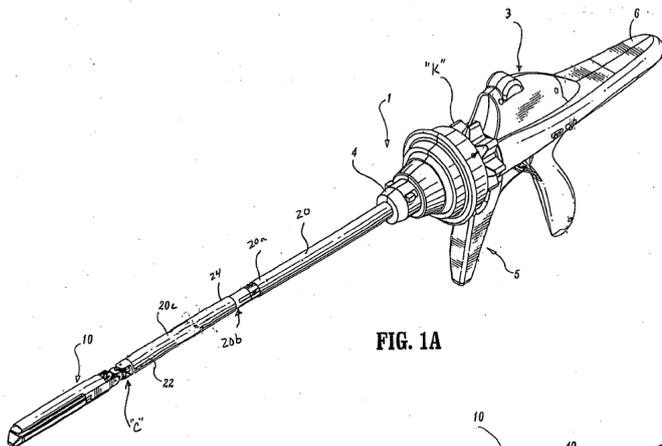


FIG. 1A

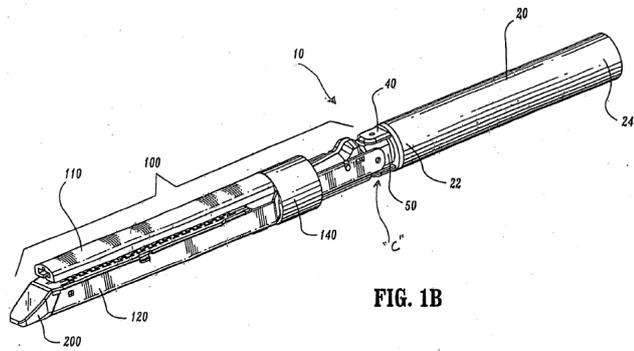


FIG. 1B

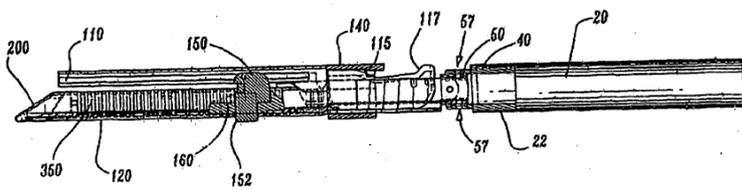


FIG. 4

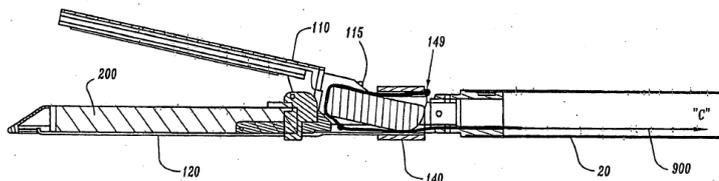


FIG. 13

The surgical stapler comprises a tool assembly (100) with an anvil assembly (110) and a cartridge assembly (200) having a plurality of staples, the anvil assembly and the cartridge assembly having an open position and an approximated position.

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 the tissue is cut, two rows of staples can be applied at each side of the cut.

The claimed invention also features a dynamic clamping member (150) with an upper camming surface which engages the anvil assembly and a lower camming surface which engages the cartridge assembly, a sled (160) for forcing the plurality of staples to deform against a bottom surface of the anvil assembly, a pre-clamping collar (140) to move the anvil assembly and the cartridge assembly between the open position and the approximated position, and a pivot block (50) attached to the tool assembly and an elongate shaft (20) for pivoting the tool assembly about a Z axis and a Y axis perpendicular to an X axis defined by the elongate shaft.

2. Extension of subject-matter

2.1 The appellant argued that the objections of added subject-matter against the main request should not be admitted into the appeal proceedings because the respondent had raised no such objections against a corresponding request in the first-instance proceedings.

However, as the respondent pointed out, objections of added subject-matter were raised against claim 1 of the main request in the first-instance proceedings. These objections correspond to the objections raised by the respondent on appeal and apply to features of claim 1 of the main request on appeal present in claim 1 of the main request in the first-instance proceedings. The statements in the impugned decision and the minutes of the oral proceedings before the Opposition Division according to which the respondent had no objections of added subject-matter against the request corresponding to the main request on appeal mean, in context, that the respondent did not have any objections other than the ones already considered and found not convincing by the Opposition Division. In the absence of a specific indication, it cannot be assumed that the opponent withdrew those objections.

Hence, in accordance with Article 12(4) RPBA 2007, the objections of added subject-matter presented by the respondent on appeal are in the proceedings.

2.2 The original application and the other parent applications contain the description, drawings and claims of the first parent application as filed (the claims in the form of clauses at the end of the description). It follows that extension of

subject-matter can be assessed only by referring to the first parent application as filed.

In the first parent application as filed, the subject-matter of claim 1 of the main request is based on, for the definition of the tool assembly: page 14, second paragraph to page 15, first paragraph; for the definition of the dynamic clamping member: page 7, third paragraph and the paragraph bridging pages 28 and 29; for the definition of the sled: claim 9; for the definition of the pre-clamping collar: the paragraph bridging pages 15 and 16, the paragraph bridging pages 28 and 29 and page 32, first paragraph; and for the definition of the pivot block: claim 9, page 5, second full paragraph and page 11, first full paragraph.

- 2.3 The respondent argued that the subject-matter of claim 1 of the main request included added subject-matter because it comprised a number of unallowable intermediate generalisations.

The Board notes that intermediate generalisations arising from the omission of features in an originally disclosed combination are allowable if there is no technically inextricable link between the omitted features and the claimed features.

- 2.4 As explained above, claim 9, page 5, second full paragraph and page 11, first full paragraph of the first parent application as filed disclose a pivot block. One of the respondent's objections relates to the omission in claim 1 of the main request of a tubular connector which mounted the pivot block allowing pivotable movement of the tool assembly about a Y axis and a Z axis defined perpendicular to a longitudinal X axis.

The Board cannot conclude that a specific connection between the pivot block and the elongate shaft by means of a tubular connector is technically inextricably linked with the function of the pivot block, i.e. enabling the pivoting of the tool assembly about two axes.

Claim 1 specifies that the pivot block is attached to the elongate shaft and enables the pivoting of the tool assembly. Hence, claim 1 prescribes some connector between the pivot block and the elongate shaft. The person skilled in the art immediately recognises that connectors with shapes other than tubular, and not necessarily including flanges and pins, can provide the pivotal movement of the pivot block as defined in claim 1 of the main request.

It follows that the omission of the tubular connector does not add subject-matter.

2.5 The tool assembly is disclosed on page 14, second paragraph to page 15, first paragraph of the first parent application as filed. The respondent objected to claim 1 of the main request omitting a channel assembly.

However, the first three lines of the last paragraph of page 5 of the first parent application as filed, which belong to the summary of the invention referred to by the appellant, generally state that the tool assembly preferably includes a channel assembly. Hence, the first parent application as filed teaches that this feature is merely optional. Moreover, the first parent application as filed does not inextricably link the features of the claim directed to the manipulation of

an anvil assembly and a cartridge assembly as such with a two-part cartridge assembly, comprising a channel assembly and a staple cartridge.

It follows that the omission of the channel assembly does not add subject-matter either.

- 2.6 Page 7, third paragraph and the paragraph bridging pages 28 and 29 of the first parent application as filed disclose the dynamic clamping member with camming surfaces. The respondent argued that there was no basis for the general definition of the camming surfaces of the dynamic clamping member engaging the anvil and cartridge assemblies and configured to oppose expansive forces in claim 1 of the main request.

However, as the appellant pointed out, independent claims 1 and 19 of the first parent application as filed do not specify any structure of the interfaces of the dynamic clamping member, or of their engagement with the anvil and cartridge assemblies, for the function of opposing expansive forces as defined in claim 1 of the main request. Page 28, last three lines, and page 29, first four lines of the first parent application as filed, which teach various mechanical options for the camming surfaces of the dynamic clamping member, also indicate that there is no inextricable link between the claimed function of opposing expansive forces and a particular technical implementation for achieving this function. The person skilled in the art is aware of various technically equivalent alternatives. As regards the alleged difference between the term "configured" and the term "arranged", this is only a literal one. Technically, both terms define equivalent functional limitations for the person skilled in the art.

It follows that the first parent application as filed provides a basis for the definition of the camming surfaces of the dynamic clamping member according to claim 1 of the main request.

- 2.7 The respondent also objected to the omission of the definition of the vertical registration of the camming surfaces for providing the functional feature of maintaining a substantially uniform gap as recited in claim 1 of the main request.

However, page 7, last paragraph of the first parent application as filed, which discloses the provision of a substantially uniform gap between the anvil and the staple cartridge, does not mention the vertical registration of the camming surfaces. Hence, the omission of the vertical registration of the camming surfaces from claim 1 of the main request is allowable.

- 2.8 In conclusion, the objections of added subject-matter (Articles 76(1), 123 (2) and 100(c) EPC) raised by the respondent do not prejudice the maintenance of the patent on the basis of the main request.

3. Inventive step

- 3.1 The respondent argued that the subject-matter of claim 1 of the main request lacked an inventive step when starting from D1, D2 or D3 in combination with D4 or D5.

It is common ground that each of D1 to D3 discloses a surgical stapler with a pre-clamping collar for moving an anvil assembly and a cartridge assembly between an open position and an approximated position.

anvil portion (140) and a cartridge assembly (150).

By actuating a closure channel (138), the anvil portion and the cartridge assembly can be approximated (column 9, lines 13 to 22). Closure channel 138 can be considered a pre-clamping collar within the meaning of claim 1 of the main request. D2 comprises several embodiments which permit articulation of the tool assembly with respect to the shaft portion. For example column 4, lines 31 to 41 disclose an articulating coupling device in the form of a ball-in-socket type coupling.

It is common ground that none of D1 to D3 discloses a dynamic clamping member as defined in claim 1 of the main request.

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 of providing 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, put forward by the respondent, is not acceptable as the objective technical problem as it comprises elements of the claimed solution.

3.1.1 One embodiment of D4 discloses a first mechanism for gross approximation of the anvil assembly and the

cartridge assembly in the form of a distally located cable 44 and a dynamic clamping member as defined in claim 1 of the main request in the form of an I-beam (70) with camming surfaces 82a and 82b.

However, D4 teaches a tool assembly for gastro-oesophageal lesions. Cable 44 is of no hindrance for the field of application of D4 but would make the assemblies of any of D1 to D3 useless for the treatment of blood vessels because it would hinder the introduction of tissue from the distal side of the assembly. Moreover, the mechanical design of the clamping mechanisms of D1 to D3 would make it difficult to implement only the I-beam of the approximation mechanism disclosed in D4. The person skilled in the art would instead transfer the whole approximation mechanism of D4, which does not include a pre-clamping collar for performing gross approximation, also because D4 explains no advantages deriving from the quick removal of fluid from the tissue in the area of further clamping (to which the appellant referred). Finally, there is no teaching in D4 on the objective technical problem. The respondent's argument that the person skilled in the art would readily recognise that a dynamic clamping member as disclosed in D4, because of its structure, would improve the accuracy of the stapling process is a mere allegation. Hence, the person skilled in the art would have had no obvious reason for implementing the I-beam member of D4 in the stapler of any of D1 to D3.

- 3.1.2 D5 discloses a surgical stapler which, according to one embodiment, comprises a spring (column 4, lines 9 to 17) for performing gross approximation of an anvil assembly and a cartridge assembly. According to the passage in column 4, "the anvil would then be loosely

clamped on the tissue" until a further actuation mechanism is actuated to more firmly and progressively clamp the tissue as the fasteners are fired.

This further actuation mechanism is illustrated as 50 in Figure 2 reproduced below and described in column 4, lines 32 to 42.

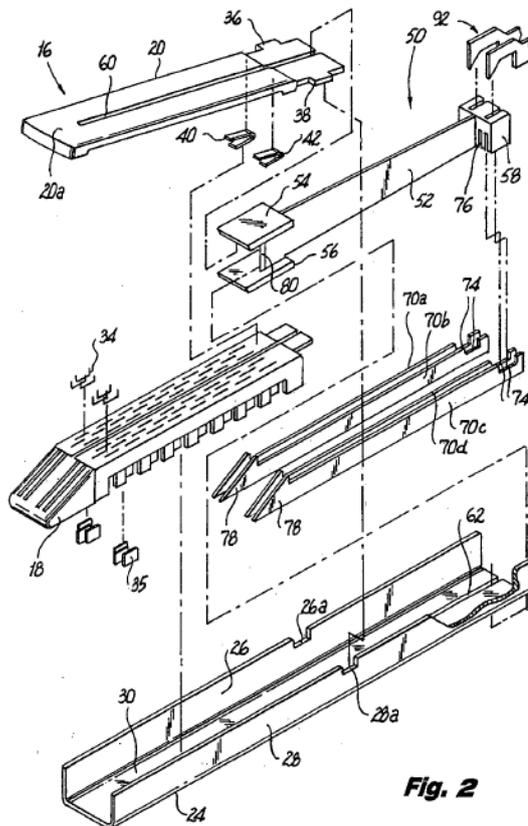


Fig. 2

Actuation mechanism 50, which is for performing fine approximation of the anvil assembly and the cartridge assembly, comprises camming surfaces 54 and 56 and falls within the definition of the dynamic clamping member according to claim 1 of the main request.

However, the mechanical design of the clamping mechanisms of D1 to D3 would make it difficult to implement only actuation mechanism 50 of the approximation mechanism disclosed in D5. The

respondent's argument that there was no technical difficulty in doing so, in particular starting from D2, is not accepted. Although both D2 and D5 disclose articulated staplers, the articulation joints involved in the approximation of the cartridge assembly and the anvil assembly are different and would need substantial adaptation. The person skilled in the art would instead transfer the whole approximation mechanism of D5, which does not include a pre-clamping collar for performing gross approximation, also because D5 explains no advantages deriving from the quick removal of fluid from the tissue in the area of further clamping (to which the appellant referred). Finally, there is no teaching in D5 on the objective technical problem. There is no reason to assume that the person skilled in the art would readily recognise that the addition of a dynamic clamping member as disclosed in D4, because of its structure, would improve the accuracy of the stapling process. Hence, the person skilled in the art would have had no obvious reason for implementing the actuation mechanism 50 of D5 in the stapler of any of D1 to D3.

- 3.2 The opponent argued that the subject-matter of claim 1 of the main request lacked an inventive step starting from D4.

D4 discloses a surgical stapler with an actuation mechanism for performing gross approximation of a pair of jaws (Figures 3, 12, 13, 15 and 16 and paragraph [0035], second and third sentence).

According to D4, which is specifically related to the treatment of gastro-oesophageal 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 clamping collar for performing fine approximation of the jaws (paragraph [0036]).

It is common ground that D4 does not disclose a pre-clamping collar positioned adjacent to the proximal end of the cartridge assembly and the anvil assembly that is movable to move the anvil assembly and the cartridge assembly between the open position and the approximated position.

The possibility of using a pre-clamping collar adjacent to the proximal end of the cartridge assembly and the anvil assembly, as defined in claim 1 of the main request, for moving these assemblies between open and approximated positions instead of a cable at the distal side of the tool assembly as disclosed in D4 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. Hence, the respondent's argument that a pre-clamping collar as claimed was equivalent to the actuation cable of D4 is not correct.

As a consequence, the objective technical problem solved by the distinguishing feature is not the problem of providing an alternative gross approximation mechanism, as put forward by the respondent, but rather facilitating the manipulation of tissue.

It is accepted that D1 to D3 disclose a clamping collar for moving an anvil assembly and a cartridge assembly between open and approximated positions. It is also accepted that such clamping collars are known in the

field of surgical staplers from other documents such as D9, D10 and D11.

However, D1 to D3 do not disclose a mechanism for performing gross approximation first followed by fine approximation like the one disclosed in D4. The clamping collars disclosed in D1 to D3 are used to perform a one-step approximation. The other documents disclosing clamping collars do not teach a two-step approximation mechanism either.

The respondent's argument that it would have been routine practice to replace the cable and its activation mechanism in D4 with a clamping collar as disclosed in D1 to D3 or the other cited prior art is not accepted. The person skilled in the art would have received no teaching to replace an element of the two-step approximation mechanism of D4 from documents which do not disclose such a mechanism and do not address the objective technical problem. In view of the objective technical problem, the person skilled in the art could have simply replaced the whole mechanism of D4 with a one-step approximation mechanism including a clamping collar.

Hence, starting from D4 in combination with any of D1 to D3 or the other documents cited by the respondent, the subject-matter of claim 1 of the main request would not have been arrived at in an obvious way.

3.3 It follows that the objections of lack of inventive step (Article 56 EPC) raised by the respondent do not prejudice the maintenance of the patent on the basis of the main request.

4. The proprietor filed an amended paragraph of the description to bring it into conformity with the claims of the main request. The opponent had no objections to this amendment. The Board does not have any either.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the Opposition Division with the order to maintain the patent as amended in the following version:
 - claims 1 to 8 of the main request filed with the letter dated 8 April 2015
 - description: paragraphs [0001] to [0009] and [0011] to [0059] of the patent specification and paragraph [0010] as filed during the oral proceedings before the Board
 - the drawings of the patent specification

The Registrar:

The Chairman:



A. Chavinier-Tomsic

M. Alvazzi Delfrate

Decision electronically authenticated