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Datasheet for the decision of 20 October 2022

Case Number: T 1794/16 - 3.2.02

Application Number: 10006462.5

Publication Number: 2229894

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), 83, 100(a), 100(b), 100(c), 123(2)

Keyword:
Sufficiency of disclosure - (yes)
Added subject-matter - (no)
Inventive step - (yes)

Decisions cited:
G 0001/03, G 0003/14, T 0113/86, T 0416/86, T 0301/87, T 0515/00, T 0593/09

Catchword:

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Case Number: T 1794/16 - 3.2.02

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

Appellant: (Patent Proprietor)	Covidien LP 15 Hampshire Street Mansfield, MA 02048 (US)
Representative:	Zimmermann & Partner Patentanwälte mbB Postfach 330 920 80069 München (DE)
Appellant: (Opponent)	ETHICON ENDO-SURGERY, INC. 4545 Creek Road Cincinnati, Ohio 45242-2839 (US)
Representative:	Carpmaels & Ransford LLP One Southampton Row London WC1B 5HA (GB)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 3 June 2016 concerning the maintenance of European Patent No. 2229894 in amended form**

Composition of the Board:

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

Summary of Facts and Submissions

I. The patent proprietor and the opponent appealed against the Opposition Division's decision that, account being taken of the amendments made by the patent proprietor according to the second auxiliary request, the patent and the invention to which it related met the requirements of the EPC. The main request and the first auxiliary request were not allowed for added subject-matter.

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.

III. The appellant/patent proprietor ("the proprietor") requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request filed with letter dated 5 October 2016 or, in the alternative, on the basis of one of auxiliary requests 1, filed with letter dated 5 October 2016, and 2 or 3, both filed with letter dated 20 February 2017.

IV. The appellant/opponent ("the opponent") requested that the decision under appeal be set aside and that the patent be revoked.

V. The following documents are relevant to this decision:

E1: US 2002/0143346 A1
E2: US 5,865,361 A
E3: US 5,653,374 A
E4: US 5,485,952 A
E5: EP 0 741 996 A2
E6: US 5,312,023 A
E7: US 6,032,849 A
E8: EP 0 640 317 A1

VI. 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, the anvil assembly being made from a heavy gauge material and the cartridge assembly being mechanically mounted in a channel assembly (120) having a bottom wall (128), wherein the anvil assembly has a longitudinally disposed slot (112) defined therethrough and the channel assembly has a longitudinally disposed slot (126) defined through said bottom wall; and

a dynamic clamping member (150) having an upper camming surface (159) and a lower camming surface (152) and a central support (151) extending upwardly from the lower camming surface, the upper camming surface and the lower camming surface being substantially vertically aligned, the upper camming surface and the lower camming surface riding between the anvil assembly and the cartridge assembly, the upper camming surface (159) slidingly engaging the anvil assembly (110), the lower camming surface (152)

slidingly engaging the bottom wall (128), and the central support (151) translating within the longitudinal slot in the channel assembly upon movement of the dynamic clamping member; and

a clamping collar (140) for moving the anvil assembly and cartridge assembly between the open and approximated positions."

Claims 2 to 13 are dependent claims.

VII. The opponent's arguments relevant to the decision can be summarised as follows.

Sufficiency of disclosure

The feature of the anvil assembly being made from a "heavy gauge material" in claim 1 of the main request was not sufficiently disclosed. In ordinary use, "heavy gauge" meant "really thick". There was no reason to depart from the ordinary meaning of the words in this case. The claims and the description did not allow the skilled person to assess which material and which thickness were required for the anvil assembly of the claimed stapler. Hence, claim 1 of the main request was so ill-defined that it was impossible to establish whether a given anvil assembly lay within the scope of the claim. This resulted in a lack of sufficiency under case law (e.g. T 593/09). According to the patent, one example of a material for the anvil assembly was 301 surgical stainless steel. However, "heavy gauge" was used as a qualifier of surgical steel (paragraphs [0048] and [0055]), meaning there was no identity between "heavy gauge" and surgical steel. Moreover, surgical steel could be thin or thick or something in between.

Claim 1 of the main request encompassed embodiments in which the dynamic clamping member was able to move before or at the same time as the clamp collar and embodiments in which the dynamic clamping member could be actuated without pre-clamping. 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.

Extension of subject-matter

Claim 1 of the main request extended beyond the content of the parents and the original application as filed. The prohibition of extension beyond the content of the parents and the original application as filed was a strict requirement. The slightest doubt about the original disclosure of the claimed subject-matter meant that this requirement was not met (T 113/86).

No camming surfaces of the anvil for cooperation with the clamping collar were defined in the claim. Instead, a general interaction between the clamp collar and the anvil assembly was defined. However, on the basis of the parents and the original application, it was clear to the person skilled in the art that the camming surface of the anvil was essential to the invention. The parents and the original application as filed only provided one way to enable pre-clamping, i.e. through the camming interaction between the camming surface of the anvil and the clamping collar. The definition of a functional feature instead of the originally disclosed structure for performing the function added subject-matter (T 416/86, Headnote) in the form of a non-allowable intermediate generalisation.

Claim 1 did not define that the upper camming surface of the dynamic clamping member was disposed in a longitudinally disposed, elongated cross or T-shaped slot in the anvil assembly. However, the parent applications and the original application disclosed this structure for the interaction between the dynamic clamping member and the anvil assembly, which served the purpose of opposing forces associated with the compression of tissue (paragraph bridging pages 21 and 22 of the first parent application as filed). Hence, a further non-allowable intermediate generalisation had been inserted into the claim.

Claim 1 did not define a sled either. According to the parents and the original application as filed, the sled was essential to the stapling function of the surgical stapler. The sled was included in each independent claim of the first parent application as filed. The fact that page 16, lines 20 to 22 of the first parent application as filed suggested that the cam wedges of the sled could be associated with the dynamic clamping member did not mean that the function provided by the sled and the corresponding structural features was optional. There was no disclosure that the sled could be omitted in its entirety. Moreover, the sled restricted the movement of the dynamic clamping member and was essential for its longitudinal movement and, hence, for providing a uniform gap between the anvil assembly and the cartridge assembly.

Claim 1 of the main request also added subject-matter because it failed to recite a stapler that had structural and/or functional technical features that brought about a prescribed order of operation by which the clamping collar acted to approximate the anvil assembly and cartridge assembly before the dynamic

clamping member rode between these. The claim covered a surgical stapler configured to enable the dynamic clamping member to ride between the anvil assembly and the cartridge assembly while the anvil assembly and cartridge assembly are in an open configuration. There was no disclosure in the parents or the original application as filed for such a stapler. It followed that a further non-allowable intermediate generalisation had been inserted.

Inventive step

The subject-matter of claim 1 of the main request lacked an inventive step starting from E1 in combination with any of E2 to E8. E1 disclosed a clamping collar 60 which could be used to approximate an anvil assembly and a cartridge assembly, as discussed in paragraph [0036] of E1. If the Board considered that E1 did not disclose a clamping collar for moving the anvil assembly and the cartridge assembly between an open position and an approximated position, it had to be considered that E1 included a gross clamping mechanism embodied as a cable 44 (paragraph [0035], Figures 3 and 12). The person skilled in the art would have appreciated that the cable 44 may interfere with tissue grasping and that a separate tissue grasping device was required (Figures 2b and 2c). This would have prompted the person skilled in the art to look for an alternative tissue clamping mechanism that facilitated tissue grasping. E4 disclosed a selectively movable clamp collar 90 (Figure 8) for moving an anvil assembly 18 and a cartridge assembly 16 between an open position and an approximated position. The clamping activation mechanism of E4 was similar to the activation mechanism of cable 44 of E1. It would have been routine practice

to replace the cable and its activation mechanism with the clamp collar 90 and its related activation mechanism of E4. The same held true in view of E5, which disclosed a clamp collar 38 configured to close the jaws of a surgical stapler.

The subject-matter of claim 1 of the main request lacked an inventive step also starting from E4 or E8 in combination with E1, E2, E3 or E7. E4 disclosed a surgical stapler (Figures 1, 4, 8 and 10) that comprised an anvil assembly 18, a cartridge assembly 16 and a channel assembly 250 as defined in claim 1 of the main request. E4 did not disclose a dynamic clamping member as claimed. The use of such a dynamic clamping member to oppose expansive forces associated with clamping and stapling tissue was known from E1 (I-beam member 70), E2 (Figures 30 and 45), E3 (Figures 4 and 11) and E7 (Figure 3). The person skilled in the art aiming to improve the performance of the surgical stapler of E4 would have been motivated to modify it to include a dynamic clamping member as disclosed in E1, E2, E3 and E7 also because there was no technical hindrance in incorporating such a dynamic clamping member in the surgical stapler of E4. E8 also disclosed a surgical stapler from which the subject-matter of claim 1 of the main request differed by including a dynamic clamping member as claimed. Hence, starting from E8, to improve the tissue clamping and stapling performance of the surgical stapler, the person skilled in the art would have turned to the dynamic clamping member of E1, E2, E3 or E7 and provided a surgical stapler that had all the features of claim 1 of the main request.

The subject-matter of claim 1 of the main request lacked an inventive step also starting from E2 in

combination with E4. E2 disclosed a surgical stapler that had all the features of claim 1 except the feature of the clamping collar. This feature was disclosed in E4. It would have been normal practice to incorporate the clamping mechanism of E2 with the clamp collar 90 and its activation mechanism of E4 since the mechanism of E4 was compatible with the configuration of the surgical stapler of E2.

VIII. The proprietor's arguments relevant to the decision can be summarised as follows.

Sufficiency of disclosure

The objection against the feature of the "heavy gauge material" of the anvil assembly in claim 1 of the main request related to clarity; not sufficiency of disclosure. The patent disclosed a material for making the anvil assembly, i.e. 301 surgical stainless steel (paragraph [0029]). The person skilled in the art would understand that the patent is teaching to use a material such as 301 surgical stainless steel and to use the material in a sufficiently heavy gauge for the use of the stapler as claimed. To minimise distortion, the person skilled in the art could simply use the thickest gauge of 301 stainless steel practicable for a device of a given size.

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 moved in sliding engagement with the anvil assembly and the cartridge assembly. This was only possible 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 irreproducible merely because a claim encompassed hypothetical embodiments laying outside the breadth of the claim (T 515/00).

Extension of subject-matter

Claim 1 did not include added subject-matter.

The gist of the invention was the provision of a clamping collar in combination with a dynamic clamping member, as disclosed on page 34, lines 9 to 13 of first parent application as filed.

The paragraph bridging pages 15 and 16, which explained how the claimed invention worked, did not mention any camming surface of the anvil. Also, page 6, lines 4 to 5 of the first parent application as filed made clear that the camming surface of the anvil was optional as it was disclosed for "another embodiment".

Page 6, lines 7 to 12 and dependent claims 2 and 3 of the first parent application as filed made clear that the slot in the anvil assembly was merely a preferred feature.

The disclosure of the last three lines of page 16 of

the first parent application as filed made clear that the sled could be omitted since its function could be performed by the dynamic clamping member.

Claim 1 also prescribed that the clamping collar, in operation, had to move before the dynamic clamping member. The claim stated that the dynamic clamping member moved in sliding engagement with the anvil assembly and the cartridge assembly. This was only possible 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. This was also disclosed in the first parent application as filed.

Inventive step

The subject-matter of claim 1 of the main request was inventive in view of the combination of E1 with any of E2 to E8. E1 did not disclose a clamp collar for moving an anvil assembly and a cartridge assembly between an open and an approximated position. The clamp collar 60 of E1 was disclosed only for "finely approximating" the anvil assembly and the cartridge assembly after they had been pre-clamped around the tissue using an actuation cable 44 at the distal end of the anvil assembly and the cartridge assembly. Cable 44 obstructed the insertion of tissue into the gap between the anvil assembly and the cartridge assembly. Starting from E1, one technical problem addressed by the claimed invention was to eliminate the actuation cable by providing an alternative arrangement to move the anvil assembly and the cartridge assembly from the open position to the approximated position and to maintain them in proper alignment during stapling. Even in view

of E4, E5 or E8, it would not have been obvious to use the clamp collar 60 in conjunction with a suitable cam surface on the anvil for this purpose because the collar would only fix the positions of the anvil assembly and the cartridge assembly at their proximal ends, and there would still be excessive movement at their distal ends during stapling due to the forces generated by the stapling operation.

E4 described a surgical stapler having a clamping collar to move an anvil assembly and a cartridge assembly from an open position to an approximated position. However, E4 did not disclose a dynamic clamping member in accordance with claim 1 of the main request. The distinguishing feature solved the technical problem of sufficiently maintaining the anvil assembly and the cartridge assembly in the desired, fixed spacing and orientation when they were subjected to the forces associated with stapling. Although dynamic clamping members similar to those of the invention were disclosed in E1, E2, E3 and E7, there was no teaching in these documents that the technical problem was to be solved by a dynamic clamping member. Moreover, a fundamental redesign of the stapler of E4 would have been needed to include a dynamic clamping member as claimed. Hence, the subject-matter of claim 1 of the main request was inventive when starting from E4 in combination with E1, E2, E3 or E7. The disclosure of E8 was similar to that of E4. Hence, for the same reasons, the subject-matter of claim 1 of the main request was inventive also when starting from E8 in combination with E1, E2, E3 or E7.

E2 disclosed a surgical stapler without a clamping collar. A technical problem starting from E2 was that it was difficult to optimise both the clamping and the

stapling operations with a single dynamic clamping member performing both functions. There was no teaching in E4 that the provision of an additional clamping collar solved this problem. E4 taught a clamping collar for approximating the anvil assembly and the cartridge assembly. This function was performed by the dynamic clamping member in E2. The person skilled in the art would have had no motivation to provide an additional closing mechanism in the form of a clamping collar. Hence, the subject-matter of claim 1 of the main request was inventive also when starting from E2 in combination with E4.

Reasons for the Decision

1. The invention

The invention relates to a surgical stapler, which is typically 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 surgical stapler according to the invention.

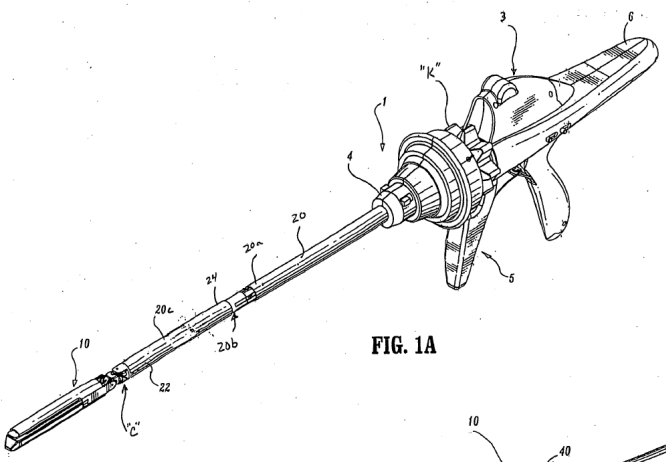

FIG. 1A

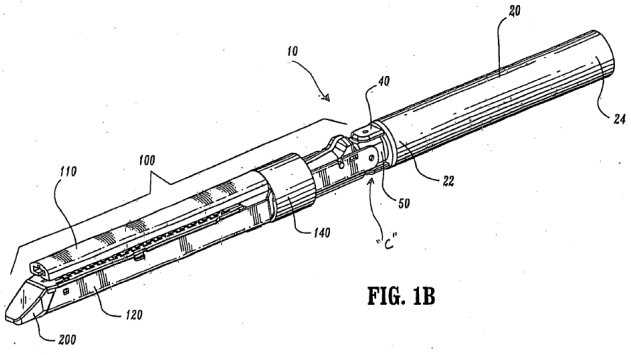

FIG. 1B

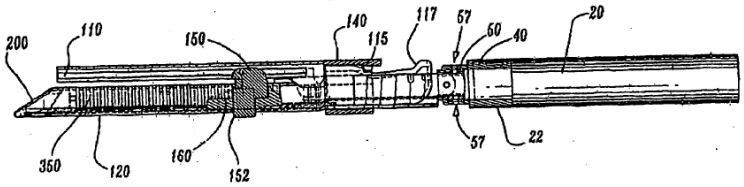

FIG. 4

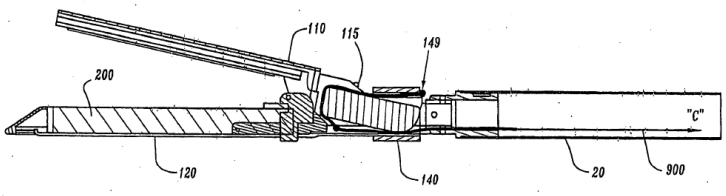

FIG. 13

The surgical stapler comprises a tool assembly (100) with an anvil assembly (110) and a cartridge assembly (200) mounted in a channel assembly and 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 and a lower camming surface riding between the anvil assembly and the cartridge assembly and a clamping collar (140) to move the anvil assembly and the cartridge assembly between the open and the approximated positions.

2. Sufficiency of disclosure

2.1 The opponent submitted that the subject-matter of claim 1 of the main request was not sufficiently disclosed because the feature "heavy gauge material" was so ill-defined that it was impossible to establish whether a certain anvil assembly lay within the scope of the claim.

The patent explains that the "heavy gauge material" of the anvil assembly could be "301 surgical stainless steel" or other high-strength and durable materials (paragraph [0029]). Therefore, the person skilled in the art receives teaching on the properties of the material of the anvil assembly. As regards the required thickness of the material, implied by the qualifier "heavy gauge" in the opponent's view, this is not specified in the patent. However, the person skilled in the art understands that this must be such for the surgical stapler to effectively perform its function. Hence, on the basis of the disclosure of the patent, the required thickness can easily be established in view of common general knowledge and, if needed, with some trial and error.

It follows that whether it can be established with certitude if a certain anvil assembly lies within the scope of the claim, as the opponent argued, is at most a matter of clarity in this case, in accordance with T 593/09, point 4.1.4 of the Reasons. Objections of lack of clarity which do not arise owing to amendments cannot be considered by the Board in opposition appeal proceedings (G 3/14, order).

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

2.3 The Board does not accept this argument.

2.4 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 proprietor 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 opponent fall within the scope of the claim.

2.5 In any case, Article 83 EPC requires that the invention 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 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 proprietor, comes to the same conclusion.

2.6 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 opponent, 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.

2.7 It follows that the ground for opposition of insufficiency of disclosure (Article 100(b) EPC) raised by the opponent does not prejudice the maintenance of the patent on the basis of the main request.

3. Extension of subject-matter

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 (i) for the definition of the tool assembly: the paragraph bridging pages 6 and 7; page 14, second paragraph to page 15, first paragraph; the paragraph bridging pages 18 and 19; and page 24, first full paragraph; (ii) for the definition of the dynamic clamping member: the paragraph bridging pages 19 and 20; and the paragraph bridging 28 and 29; and (iii) for the definition of the clamping collar: the paragraph

bridging pages 15 and 16.

3.1 The opponent argued that the subject-matter of claim 1 of the main request included added subject-matter because it comprised a number of 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 extracted from the combination. This is not in contrast with T 416/86 (point 2.1 of the Reasons), cited by the opponent. The absence of an inextricable link implies a direct and unambiguous teaching to the person skilled in the art, who is left in no doubt (in accordance with T 113/86 cited by the opponent) that features equivalent to the omitted ones - and part of the common general knowledge - can equally be used for the technical functions of the claimed features extracted from the combination.

3.2 As explained above, a clamping collar for moving the anvil assembly and cartridge assembly between the open and approximated positions is disclosed in the paragraph bridging pages 15 and 16 of the first parent application as filed. One of the opponent's objections relates to the omission in claim 1 of the main request of camming surfaces of the anvil for cooperation with the clamping collar.

However, the person skilled in the art understands that what is technically important for the function of the clamping collar is the possibility of moving the anvil assembly and the cartridge assembly from and to the

approximated position. Nowhere are camming surfaces of the anvil presented as essential for the function of the clamping collar in the first parent application as filed. The paragraph bridging pages 15 and 16, which describes the operation of the claimed invention, does not mention camming surfaces of the anvil. As the proprietor pointed out, the person skilled in the art directly and unambiguously understands, on the basis of this passage, that the movement of the anvil assembly and the cartridge assembly from and to the approximated position could equally be achieved by a number of different elements of the clamping collar, the anvil and/or the cartridge assembly. Hence, there is no inextricable link between the omitted camming surfaces and the features of claim 1 of the main request.

3.3 The upper camming surface of the dynamic clamping member is disclosed in the paragraph bridging pages 28 and 29. The opponent objected to claim 1 of the main request omitting that the upper camming surface of the dynamic clamping member was disposed in a longitudinally disposed, elongated cross or T-shaped slot in the anvil assembly.

It is true that claim 1, while stipulating that the anvil assembly has a longitudinally disposed slot, does not define the shape of the slot. However, the engagement of the upper camming surface of dynamic clamping member with the anvil assembly, as shown in the embodiment according to Figure 5 and discussed in the paragraph bridging pages 21 and 22 of the first parent application as filed, is merely preferred. Indeed, the second paragraph on page 6 describing the interaction of the camming surface and the slot does not specify the shape of the slot. It is thus clear to the person skilled in the art that several shapes of

the slot are possible for the interaction with the upper camming surface of the dynamic clamping member. Hence, this objection is not convincing either.

3.4 While the dynamic clamping member is disclosed in claim 1 of the first parent application, the features of the clamping collar were added during the examination proceedings. The opponent asserted that this addition represented an unallowable intermediate generalisation because claim 1 of the main request did not prescribe that the clamping collar acted to approximate the anvil assembly and cartridge assembly before the dynamic clamping member was moved. This added subject-matter.

As explained in point 2.2, second paragraph above, the opponent's assertion that this feature is missing from current claim 1 is questionable. In any case, disclosure for the clamping collar can be found not only in the above-mentioned paragraph bridging pages 15 and 16 but also in the claims of the first parent application as filed (claims 6, 11, 17). These claims do not specify the order of movement of the clamping collar and the dynamic clamping member. Hence, the addition of the features of the clamping collar without explicitly specifying the order of movement of the clamping collar and the dynamic clamping member does not represent an intermediate generalisation, let alone an unallowable one.

3.5 The opponent also argued that the omission of a sled in claim 1 of the main request added subject-matter.

While the opponent is right that a sled is present in every claim of the first parent application as filed, the Board notes that on page 16, last paragraph of the

first parent application as filed, it is directly and unambiguously explained that the function of the sled could be taken over by the dynamic clamping member itself. The sled is first described as including cam wedges for camming surgical fasteners into and through tissue when the sled is actuated to move by the user. Then it is explained that the dynamic clamping member is associated with the sled, for example being integral with it, and can move with the sled. Finally, it is disclosed that the dynamic clamping member itself could have the cam wedges. With such an arrangement, the presence of the sled is clearly not needed.

The opponent's argument that the sled restricted the movement of the dynamic clamping member and was essential for its longitudinal movement and for providing a uniform gap between the anvil assembly and the cartridge assembly is a mere allegation not derivable from the first parent application as filed. On the contrary, on the basis of page 16, last paragraph, the sled is directly and unambiguously disclosed as an optional feature. Its omission from claim 1 of the main request does not add subject-matter.

3.6 It follows that the objections of added subject-matter (Articles 76(1), 123 (2) and 100(c) EPC) raised by the opponent do not prejudice the maintenance of the patent on the basis of the main request.

4. Inventive step

4.1 The opponent argued that the subject-matter of claim 1 of the main request lacked an inventive step starting from E1.

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).

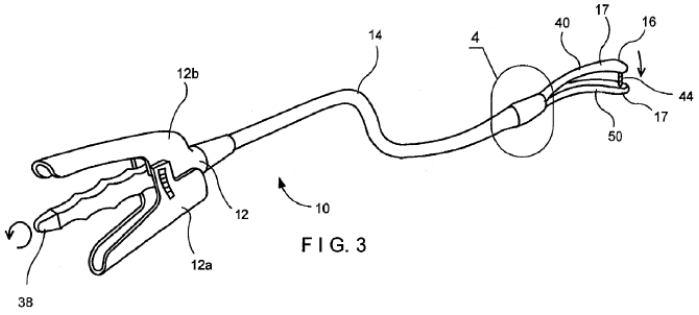

FIG. 3

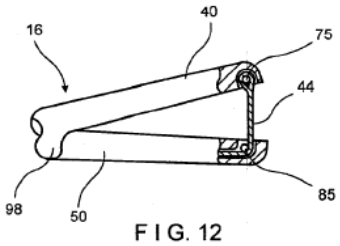

FIG. 12

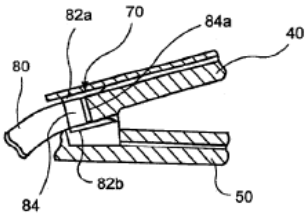

FIG. 13

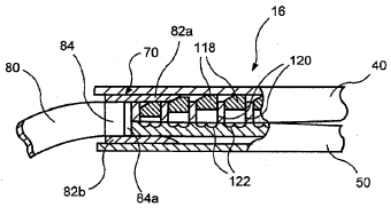

FIG. 15

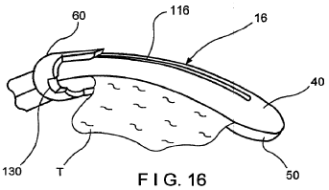

FIG. 16

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According to E1, 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]).

E1 does not directly and unambiguously disclose a clamping collar for moving an anvil assembly and a cartridge assembly between open and approximated positions as defined in claim 1 of the main request.

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. 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 7, lines 50 to 58, 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 possibility of using a clamping collar as defined in claim 1 of the main request, which inherently acts on the proximal side of the tool assembly, for moving the anvil assembly and the cartridge assembly between open and approximated positions instead of a cable at the distal side of the tool assembly as disclosed in E1 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.

It is accepted that both E4 and E5 disclose a clamping collar for moving an anvil assembly and a cartridge

assembly between open and approximated positions.

However, E4, E5 or any of E2, E3 and E6 to E8 referred to by the opponent do not disclose a mechanism for performing gross approximation first followed by fine approximation like the one disclosed in E1. The clamping collars disclosed in E4 and E5 are used to perform a one-step approximation.

The opponent's argument that it would have been routine practice to replace the cable and its activation mechanism in E1 with a clamping collar as disclosed in E4 or E5 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 E1 from documents which do not disclose such a mechanism and do not address this part of the objective technical problem. The person skilled in the art could have simply replaced the whole mechanism of E1 with a mechanism according to E4 or E5 in view of the objective technical problem.

Hence, starting from E1 in combination with any of E2 to E8, the subject-matter of claim 1 of the main request would not have been arrived at in an obvious way.

4.2 The opponent submitted that the subject-matter of claim 1 of the main request lacked an inventive step when starting from E4 or E8 in combination with E1, E2, E3 or E7.

It is common ground that both E4 and E8 disclose surgical staplers with a clamping collar for moving an anvil assembly and a cartridge assembly between open and approximated positions, but neither E4 nor E8

discloses a dynamic clamping member as defined in claim 1.

The objective technical problem solved by the dynamic clamping member is to provide a more accurate and stable stapling mechanism. This is due to the dynamic clamping member having a central support and upper and lower camming surfaces slidingly engaging the anvil assembly and the cartridge assembly respectively. This has the technical effect of opposing expansive forces associated with clamping and stapling tissue.

In accordance with one embodiment, E1 discloses 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, E1 teaches a tool assembly for gastro-oesophageal lesions. Cable 44 disclosed in E1 is of no hindrance for the 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 mechanisms of E4 and E8 would make it difficult to implement only the I-beam of the approximation mechanism disclosed in E1. E1 does not disclose a clamping collar for performing gross approximation. Finally, there is no teaching in E1 on the objective technical problem.

It is also accepted that each of E2, E3 and E7 discloses a surgical stapler with a dynamic clamping member as defined in claim 1 of the main request, as the opponent argued.

However, these documents do not disclose any clamping collar for moving an anvil assembly and a cartridge assembly between open and approximated positions. According to these documents, the dynamic clamping members are the only elements that move jaws of a surgical stapler between open and approximated positions (Figure 45 of E2, Figure 11 of E3 and Figure 7 of E7). The dynamic clamping members are not taught to solve the problem of providing a more accurate and stable stapling mechanism. E2, E3 and E7 do not suggest that the clamping should be performed by two distinct elements.

Consequently, the skilled person would not provide dynamic clamping members as disclosed in E2, E3 or E7 in the devices of E4 or E8 and, at the same time, keep the clamping collars, which are taught to perform the same function.

Hence, the subject-matter of claim 1 of the main request is inventive in view of the combination of E4 or E8 with E1, E2, E3 or E7.

4.3 The opponent also submitted that the subject-matter of claim 1 of the main request lacked an inventive step over the combination of E2 with E4.

E2 does not disclose a clamping collar as defined in the claim.

The problem solved by the clamping collar is to provide a more accurate and stable stapling mechanism. This is due to the initiation of and the contribution to the clamping action by the clamping collar.

E4 discloses a clamping collar as defined in claim 1 of

the main request. However, according to E4, the clamping collar is the only element that moves the anvil assembly and the cartridge assembly between the open and approximated positions. E4 does not teach that the clamping collar could address the problem of providing a more accurate and stable stapling mechanism. E4 does not suggest that the clamping should be performed by two distinct elements.

Consequently, the person skilled in the art would have no motivation to provide a clamping collar in addition to the dynamic clamping member of E2.

Hence, the subject-matter of claim 1 of the main request is inventive in view of the combination of E2 with E4.

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

5. 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 13 of the main request filed with the letter dated 5 October 2016
   - 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