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**Datasheet for the decision
of 15 May 2019**

Case Number: T 0663/16 - 3.2.02

Application Number: 10165409.3

Publication Number: 2238917

IPC: A61B17/072

Language of the proceedings: EN

Title of invention:

Tool assembly for a surgical stapling device

Patent Proprietor:

Covidien LP

Opponent:

ETHICON ENDO-SURGERY, INC.

Headword:

Relevant legal provisions:

EPC Art. 54, 56, 76(1), 100(a), 100(b), 100(c), 101(2),
123(2), 128(4)

EPC R. 144(d)

RPBA Art. 13(1), 13(3)

Decision of the President of the EPO of 12 July 2007
concerning documents excluded from file inspection,
Art. 1(2)

Keyword:

Inspection of files - Exclusion of documents from file
inspection (yes)

Late-filed objection - admitted (yes)

Grounds for opposition - subject-matter extends beyond
content of original or earlier application (no) -
insufficiency of disclosure (no) - novelty (yes) -
inventive step - (yes)

Decisions cited:

Catchword:



Beschwerdekammern
Boards of Appeal
Chambres de recours

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Case Number: T 0663/16 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 15 May 2019

Appellant: ETHICON ENDO-SURGERY, INC.
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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 7 January 2016
rejecting the opposition filed against European
patent No. 2238917 pursuant to Article 101(2)
EPC**

Composition of the Board:

Chairman E. Dufrasne
Members: D. Ceccarelli
S. Böttcher

Summary of Facts and Submissions

- I. The opponent has appealed against the Opposition Division's decision, despatched on 7 January 2016, to reject the opposition against European patent No. 2 238 917.
- II. The patent is derived from a divisional application of European patent application No. 08 003 414.3, which is itself a divisional of European patent application No. 03 773 180.9. The latter application as originally filed, is referred to in the following as "the first original application". The application as originally filed from which the patent is derived, is referred to in the following as "the original application".
- III. The present case is related to the case underlying decision T 1461/14, claiming priority from the first original application.
- IV. Notice of appeal was filed on 16 March 2016. The appeal fee was paid the same day. A statement setting out the grounds of appeal was received on 20 April 2016.
- V. The Board summoned the parties to oral proceedings and provided its provisional opinion in a communication of 25 January 2019.
- VI. By letter dated 13 May 2019 the respondent submitted a procedural request.
- VII. Oral proceedings took place on 15 May 2019.
- VIII. The appellant requested that the decision under appeal be set aside and that the patent be revoked.

IX. The respondent requested that the appeal be dismissed or, in the alternative, that the decision under appeal be set aside and that the patent be maintained on the basis of one of auxiliary requests 1 to 4, all filed with letter dated 2 September 2016. The respondent's request submitted by letter dated 13 May 2019 was withdrawn.

X. Both parties requested that the respondent's letter dated 13 May 2019 be excluded from file inspection.

XI. The following documents are mentioned in the present decision:

- A1: US-B-6,330,965;
- A3: US-A-5,738,474;
- A4: US-A-5,807,393;
- A5: EP-A-0 640 317;
- A6: EP-A-0 623 312;
- A9: US-A-2002/0143346;
- A11: US-A-5,040,715.

XII. **Claim 19 of the first original application** reads as follows:

"A tool assembly for use with a surgical stapler comprising:

an anvil;

a cartridge assembly having at least one staple, the cartridge assembly being movable in relation to the anvil between spaced and approximated positions;

a clamp member positioned adjacent a proximal end of the tool assembly, the clamp member being movable from a retracted position to an advanced position to move the anvil and the cartridge assembly to the approximated position; and

a dynamic damping member positioned within the tool assembly and movable from a retracted position through the tool assembly to an advanced position to eject staples from the cartridge assembly, the dynamic damping member including an upper flange portion engaging a surface of the anvil and a lower flange portion engaging a surface of the cartridge assembly, at least one of the upper and lower flange portions having an arcuate cross-section along an axis transverse to the longitudinal axis of the cartridge assembly."

Claim 1 of the patent as granted reads as follows:

"A tool assembly (12) for use with a surgical stapler, the tool assembly (12) comprising:

an anvil (14);

a cartridge assembly (16) having at least one staple and a plurality of retention slots (122), the cartridge assembly (16) being movable in relation to the anvil (14) between spaced and approximated positions, the cartridge assembly (16) further including a sled (140) and at least one pusher member (150) associated with each at least one staple;

a clamp member (20) positioned adjacent a proximal end of the tool assembly, the clamp member being movable from a retracted position to an advanced position to move the anvil and the cartridge assembly to the approximated position;

a dynamic clamping member (32) positioned within the tool assembly (12) and movable from a retracted position through the tool assembly (12) to an advanced position to eject staples from the cartridge assembly, the dynamic clamping member (32) including an upper flange portion (36a) engaging a surface of the anvil (14) and a lower flange portion (36b) engaging a

surface of the cartridge assembly (16), to maintain a desired tissue gap, the dynamic clamping (32) member being positioned proximally of the sled (140) in engagement therewith and translatable through the cartridge (16);

wherein the sled (140) has upstanding cam wedges (144) and is movable along the longitudinal axis;

the at least one pusher member (150) has a base portion (152) with a recess (154) configured and adapted for sliding engagement of at least one of the cam wedges (144), the pusher member (150) being in a fixed relationship to the longitudinal axis, the at least one cam wedge (144) engaging the recess (154) of the pusher member (150); and

longitudinal movement of the sled (140) transferring longitudinal motive forces from the at least one cam wedge (144) to the pusher member (150), thereby transferring the motive forces to the backspan (162) of the staple (160) for moving the staple (160) through the retention slot (122)."

Claim 8 of the patent as granted reads as follows:

"A tool assembly (12) for use with a surgical stapler, the tool assembly (12) comprising:

an anvil (14);

a cartridge assembly (16) having at least one staple and a plurality of retention slots (122), the cartridge assembly (16) being movable in relation to the anvil (14) between spaced and approximated positions, the cartridge assembly (16) further including a sled (140a) and at least one pusher member (150a) associated with each at least one staple;

a clamp member (20) positioned adjacent a proximal end of the tool assembly, the clamp member being movable from a retracted position to an advanced

position to move the anvil and the cartridge assembly to the approximated position;

a dynamic clamping member (32) positioned within the tool assembly (12) and movable from a retracted position through the tool assembly (12) to an advanced position to eject staples from the cartridge assembly, the dynamic clamping member (32) including an upper flange portion (36a) engaging a surface of the anvil (14) and a lower flange portion (36b) engaging a surface of the cartridge assembly (16), to maintain a desired tissue gap, the dynamic clamping (32) member being positioned proximally of the sled (140) in engagement therewith and translatable through the cartridge (16);

wherein the sled (140a) has upstanding cam wedges (144a) and is movable along the longitudinal axis, the upstanding cam wedges (144a) defining a space (146a);

the at least one pusher member (150a) has a base portion (152a) configured to reside in the space (146a) of the sled (140a) and for sliding engagement of the cam wedges (144a), the pusher member (150a) being in a fixed relationship to the longitudinal axis,; and

longitudinal movement of the sled (140a) transferring longitudinal motive forces from the at least one cam wedge (144a) to the pusher member (150a), thereby transferring the motive forces to the backspan (162) of the staple (160) for moving the staple (160) through the retention slot (122)."

Claims 2 to 7 and 9 to 14 are dependent claims.

XIII. The appellant's arguments, where relevant to the present decision, may be summarised as follows:

Request for exclusion from file inspection

The respondent's letter dated 13 May 2019 contained information that would be prejudicial to the legitimate personal or economic interests of the appellant's representatives. Since the respondent's request submitted in that letter had been withdrawn, the letter would not serve the purpose of informing the public about the patent either. It followed that that letter should be excluded from file inspection.

Added subject-matter

The tool assembly of the description and drawings of the original application did not comprise a clamp member that was movable so as to approximate the anvil and the cartridge assembly. More specifically, as explained on page 11, lines 11 to 18 of the original application, it was the movement of a dynamic clamping member that approximated the anvil and the cartridge assembly. A clamp member in the form of a clamp ring simply followed the dynamic clamping member. Each of claims 1 and 8 of the patent as granted comprised a combination of a clamp member that was movable so as to approximate the anvil and the cartridge assembly with features taken from the description of specific embodiments in the original application (pages 15 and 16), which did not include such a clamp member. Hence, there was no basis in the original application for the claimed combinations.

Moreover, the first original application referred to a preferred embodiment according to Figures 1 to 13 (page 6, first paragraph), to another preferred embodiment shown in Figure 14 (page 13, last paragraph) and to additional embodiments shown in Figures 16A

to 17B (page 15, first full paragraph). The embodiments shown in Figures 16A to 17B even comprised different reference numerals compared with the embodiment shown in Figures 1 to 13. Even if the skilled person were to interpret claim 19 of the first original application as being in conformity with the embodiment shown in Figures 1 to 13, there was no clamp member as defined in that claim in the embodiments shown in Figures 16A to 17B. Moreover, no arcuate cross-sections of the flange portions of the dynamic clamping member, which had been described extensively on page 7 of the first original application in relation to the embodiment of Figures 1 to 13, were disclosed in the embodiments of Figures 16A to 17B. Whether all these embodiments could operate in an equivalent way was not relevant for the assessment of added subject-matter. The skilled person would have at least some doubts that the embodiments shown in Figures 16A to 17B, some features of which had been introduced in claims 1 and 8 of the patent as granted, could be combined with the embodiment shown in Figures 1 to 13. It followed that claims 1 and 8 added subject-matter.

The only basis for the feature of the at least one pusher member having a base portion configured to reside in the space of the sled and for sliding engagement of the cam wedges, as defined in claim 8 of the patent as granted, could be the description, page 15, lines 20 to 22, of the first original application. That passage of the description, however, specified that the whole pusher member - not just a portion of a base - could be configured to reside within a space between cam wedges, and that a base of the pusher member was configured and adapted for sliding engagement with a space of the sled - not with the cam wedges. Figure 17B of the first original

application showed that the whole base 152a of pusher member 150a - not just a portion - resided between two cam wedges. It followed that claim 8 comprised new technical information that added further subject-matter.

Insufficiency of disclosure

The skilled person could not produce a tool assembly according to claims 1 or 8 of the patent as granted, in which the clamp member moved the anvil and the cartridge assembly into an approximated position, as the only device disclosed in the patent was one in which the dynamic clamping member, being distal of the clamp member, approximated the jaws alone. The subject-matter of claims 1 and 8 of the patent as granted was therefore insufficiently disclosed.

Lack of novelty

The subject-matter of claim 1 of the patent as granted lacked novelty over A1. In particular, A1 disclosed a surgical stapling apparatus with a drive assembly 212 that could be equated to both the claimed clamp member and dynamic clamping member, as it achieved the functions of both of those members. Based on the teaching of the patent, the skilled person would understand that both the claimed clamp member and the dynamic clamping member were the dynamic clamping member 32 mentioned in the description and drawings, since only this member moved the cartridge and the anvil to the approximated position. Alternatively, since drive assembly 212 was made of several elements, as shown in Figures 31 and 32 of A1, the left half of the assembly could be equated to the clamp member and the right half to the dynamic clamping member. This was

justified since each half of the assembly achieved the claimed functions of approximating the jaws of the surgical stapling apparatus and translating through the cartridge to eject staples, and claims 1 and 8 did not comprise any special language that required the clamp member and the dynamic clamping member to be independent features.

Lack of inventive step

The subject-matter of claims 1 and 8 lacked an inventive step when starting from A1. Although this objection had only been raised during the oral proceedings, it should be admitted, since A1 had been on file since the beginning of the appeal proceedings and had been held against novelty of the claims. If A1 was considered not to disclose a clamp member as defined in claims 1 and 8 of the patent as granted, then that distinguishing feature would have the technical effect of improving clamping, as also explained in paragraph [0030] of the patent. It followed that the objective technical problem solved over A1 was to improve clamping. Providing a clamp member in a surgical stapling device was, however, common general knowledge. The skilled person would implement such a clamp member in the surgical stapler of A1 without any inventive activity.

The subject-matter of claims 1 and 8 of the patent as granted lacked an inventive step when starting from any of A3, A4, A5 and A6. Each of these documents disclosed a tool assembly for use with a surgical stapler, from which the subject-matter of claims 1 and 8 differed in the presence of the defined dynamic clamping member. The effect of the claimed dynamic clamping member was to maintain a desired tissue gap during stapling. It

followed that the technical problem to be solved was the provision of a tool assembly in which a desired tissue gap was maintained during stapling. This was the only problem derivable from the patent. The skilled person would turn to A9, which disclosed an endoscopic surgical stapling device with an I-beam for maintaining a desired tissue gap as it was advanced through the device and a further clamping mechanism for achieving gross approximation of the jaws of the device. In view of the problem to be solved, the skilled person would introduce the I-beam of A9 into any of the devices of A3, A4, A5 and A6 in an obvious way.

The subject-matter of claims 1 and 8 of the patent as granted also lacked an inventive step when starting from A9. A9 disclosed a tool assembly for a surgical stapler, comprising a clamp member in the form of a cable (44, Figure 12) and a dynamic clamping member in the form of an I-beam (70, Figure 14). The I-beam had a leading surface that made up a sled within the meaning of claims 1 and 8. The skilled person would readily combine the teaching of A9 with that of any of A3, A4, A5 and A11, which disclosed a clamp member, and that of A6, which disclosed particular staple drive members, and arrive at the subject-matter of claims 1 and 8 in an obvious way.

XIV. The respondent's arguments, where relevant to the present decision, may be summarised as follows:

Request for exclusion from file inspection

The respondent was also of the opinion that its letter dated 13 May 2019 could be prejudicial to the legitimate personal or economic interests of the appellant's representatives, and it requested that the

letter should be excluded from file inspection.

Added subject-matter

The clamp member of the tool assembly disclosed in the description and drawings of the original application was included in the definition of components that contributed to approximating the anvil and the cartridge assembly (page 9, lines 16 to 20, of the application as filed). When reading the application as a whole, especially in view of claim 19 of the first original application, which explicitly defined a clamp member for moving the anvil and the cartridge assembly to an approximated position, the skilled person would understand that the clamp member of the embodiments disclosed in the description could serve to approximate the cartridge and the anvil assembly.

All the different embodiments disclosed in the first original application comprised clamp members and dynamic clamping members according to claim 19 of that application. They differed only in specific described details, especially in relation to their sled and pusher arrangements. It was not permissible to compartmentalise the teaching of the first original application as a whole when assessing added subject-matter.

A basis for the feature of the at least one pusher member having a base portion configured to reside in the space of the sled and for sliding engagement of the cam wedges, defined in claim 8 of the patent as granted, was provided by pages 15 and 16 of the first original application. The skilled person would understand from the application as a whole and from common general knowledge that during interaction with a

cam wedge some portion of the pusher would reside within the space between the wedges even though another portion of the pusher might extend outside that space. Figure 17B of the first original application showed that the base portion of the pusher member was configured for sliding engagement with the cam wedges and the space between them. It followed that claim 8 did not comprise any added subject-matter.

Insufficiency of disclosure

Figure 1 of the patent showed a tool assembly in which the clamp member could be advanced to move the cartridge and the anvil assembly to the approximated position by engagement with camming surface 80. An enabling disclosure of a tool assembly with a clamp member that approximates the jaws was therefore provided to the skilled person reading the patent with a mind willing to understand.

Lack of novelty

The subject-matter of claim 1 of the patent as granted was novel over A1. In particular, the claim language referred to two components: a clamp member and a dynamic clamping member. In contrast, drive assembly 212 of A1 was a single component once it had been assembled to perform its function.

Lack of inventive step

The objection of lack of inventive step when starting from A1 had been raised late. The respondent had been completely surprised by the objection. To give the respondent the right to a fair hearing, the objection should not be admitted into the appeal proceedings. A

clamp member for moving the anvil and the cartridge assembly to the approximated position in addition to the presence of a dynamic clamping member was a major technical difference in the subject-matter of claims 1 and 8 with respect to A1. The objective technical problem addressed by that difference, derivable from paragraph [0030] of the patent, in particular column 10, lines 7 to 17, was how to reduce the likelihood that staples were displaced from their intended position during their deformation. A1 did not hint at this problem, as was apparent from column 2, lines 19 to 27. The skilled person had no motivation to implement a clamp member as claimed in view of the objective technical problem.

The subject-matter of claims 1 and 8 of the patent as granted was inventive when starting from any of A3, A4, A5 and A6. None of those documents disclosed a dynamic clamping member according to those claims. The dynamic clamping member, together with the claimed clamp member and the interface between the pusher and the cam wedges, addressed the problem of improving staple alignment. A9 did not address that problem. Hence the skilled person had no motivation to combine the teaching of A9 with that of any of A3 to A6.

Starting from A9, a distinguishing feature was the sled as defined in claims 1 and 8. The I-beam disclosed in A9 was a single component, which could not be interpreted as the claimed dynamic clamping member and the sled at the same time. Since the I-beam worked as a sled to eject staples, there was no motivation for the skilled person to implement a further sled in the device of A9, especially in view of the problem of improving staple alignment.

Reasons for the Decision

1. The appeal is admissible.
2. The invention

The invention relates to a tool assembly for use with a surgical stapler comprising an anvil and a cartridge assembly having at least one staple.

Devices of the kind of the invention are typically used in laparoscopic or endoscopic procedures for splitting tissue and stapling it together. Generally, the tissue to be treated is first clamped between the anvil and the cartridge assembly and then cut through along a longitudinal direction of those two components. At the same time as the tissue is cut, staples are applied at each side of the cut.

Figure 1 of the patent, reproduced below, shows such a device.

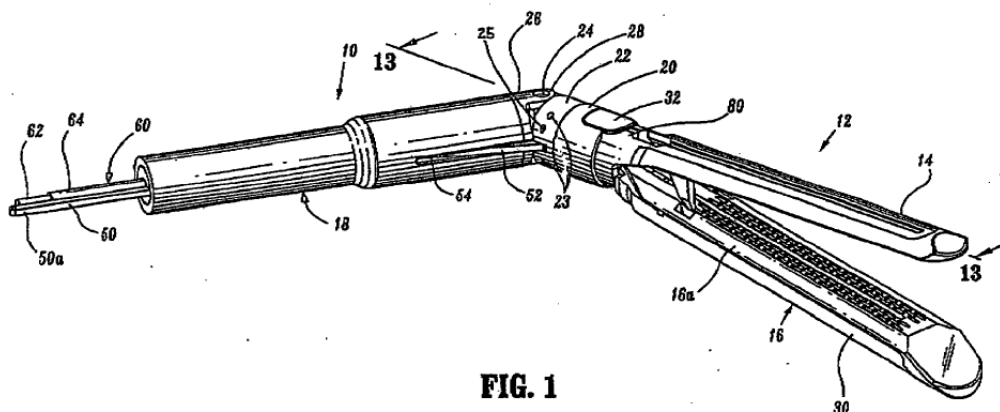


FIG. 1

The claimed invention features a clamp member (20), movable so as to bring the anvil (14) and the cartridge

assembly (16) to an approximated position, a dynamic clamping member (32) engaging the anvil and the cartridge assembly to maintain a desired tissue gap as it translates through the cartridge assembly to an advanced position to eject staples, and a sled with at least one pusher member comprised in the cartridge assembly, to eject staples.

3. As mentioned above, the patent in suit is derived from a divisional application of European patent application No. 08 003 414.3, which is itself a divisional of European patent application No. 03 773 180.9. European patent application No. 08 003 414.3 as originally filed contains the description, drawings and claims of European patent application No. 03 773 180.9 as originally filed. Compliance with Article 76(1) EPC can be assessed by only considering the first original application.

4. Request for exclusion from file inspection

Both parties requested that the respondent's letter dated 13 May 2019 be excluded from file inspection.

- 4.1 Under Article 128(4) EPC, files relating to a European patent may be inspected on request after the publication of the application, subject to the restrictions laid down in the Implementing Regulations. Under Rule 144(d) EPC, documents may be excluded from inspection by the President of the European Patent Office on the ground that such inspection would not serve the purpose of informing the public about the European patent. According to Article 1(2) of the President's decision of 12 July 2007 (Official Journal, Special Edition 3/2007, 125) documents are to be excluded from file inspection at the reasoned request

of a party or his representative if their inspection would be prejudicial to the legitimate personal or economic interest of natural or legal persons.

Under those provisions, the respondent's letter ought to be excluded from file inspection if it does not serve the purpose of informing the public about the patent and would be prejudicial to the legitimate personal or economic interest of natural or legal persons.

4.2 As regards the first condition, the Board notes that the respondent's request submitted with this letter was subsequently withdrawn. Therefore, the letter does not serve the purpose of informing the public about the patent.

4.3 The Board also accepts that elements of that letter could be prejudicial to the legitimate personal or economic interests of the appellant's representatives, since their professional conduct was called into question.

4.4 Consequently, the Board decides to exclude from file inspection the respondent's letter dated 13 May 2019, in accordance with the request of both parties.

5. Added subject-matter

Independent claims 1 and 8 of the patent as granted are derived from independent claim 19 of the first original application and additionally define the features of the sled and pushing member for ejecting the staples according to the embodiments of the first original application depicted in Figures 16A and 16B, and 17A and 17B respectively. They comprise the features of

those embodiments in relation to the ejection of the staples, as disclosed on page 15, line 3, to page 16, line 3. In addition, they are based on page 13, lines 13 to 16, for the definition of the dynamic clamping member "to maintain a desired tissue gap", page 14, lines 10 and 11, for the definition of the "plurality of retention slots" and claim 22, first part, for the definition of "the sled and at least one pusher member". Compared with claim 19 of the first original application, in claims 1 and 8 the feature of the upper and/or lower flange portions having an arcuate cross-section has been deleted. This deleted feature does not have the technical function of ejecting the staples, which is the function of the sled and the pusher member. Figures 16A to 17B are reproduced below.

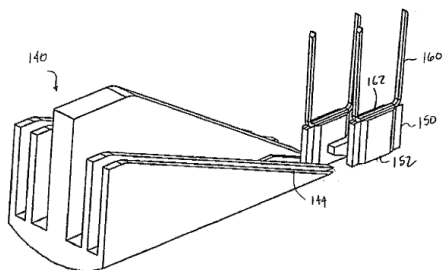


FIG. 16A

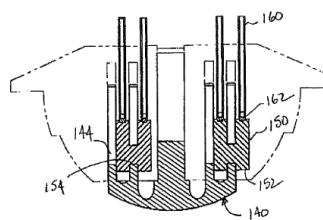


FIG. 17A

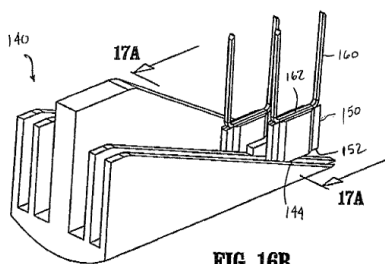


FIG. 16B

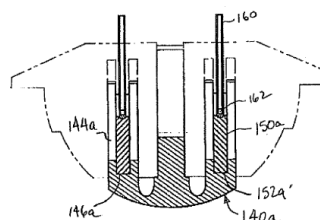


FIG. 17B

5.1 One of the appellant's objections of added subject-matter is based on an interpretation according to which the description and drawings of the first original application did not disclose any embodiment comprising a clamp member that was movable so as to

approximate the anvil and the cartridge assembly as defined in claim 19 of the first original application.

The description refers to a first preferred embodiment of the invention depicted in Figures 1 to 13 (page 6, first sentence). While the description also refers to other preferred embodiments of the invention depicted in Figures 14 to 17B (page 5, lines 9 to 19), the Board notes that those figures, compared with the first preferred embodiment, are specifically concerned with a different configuration of the dynamic clamping member (closure member 132, page 13, last paragraph) and further elements of the cartridge assembly (page 14, second paragraph). Those other embodiments are however not related to different clamp members.

It follows that, if the embodiment of Figures 1 to 13 was not according to claim 19 of the first original application because of the configuration of its clamp member, then there would be no embodiment in accordance with that claim. This has to be taken into account when interpreting the claim wording.

- 5.2 More specifically, the appellant argued that, on the basis of the second paragraph on page 11 of the first original application, it was the dynamic clamping member - not the clamp member - that moved the anvil and the cartridge assembly to the approximated position due to the engagement of the cartridge assembly with a respective flange.

While this might appear correct on a literal interpretation, what actually happens is that clamp ring 20 is moved distally together with dynamic clamping member 32. Hence, its movement towards the advanced position as defined in claim 19 of the first

original application contributes to the movement of the anvil and the cartridge assembly to the approximated position. Trying to make technical sense of that claim in view of the disclosure of the first original application as a whole, that contribution has to be interpreted as fulfilling the claim requirement of a clamp member movable so as to approximate the anvil and the cartridge assembly as defined in claim 19 of the first original application. It follows that the embodiment of Figures 1 to 13 is in accordance with and supports the invention as defined in claim 19 of the first original application.

5.3 As mentioned above, the embodiments depicted in Figures 14 to 17B, compared with the first preferred embodiment, are specifically concerned with a different configuration of the dynamic clamping member and further elements of the cartridge assembly. While they do not show all the features disclosed in the embodiment of Figures 1 to 13, as the appellant submitted, the embodiments of Figures 14 to 17B do not disclose or teach any features that may be different from or incompatible with the features defined in claim 19 of the first original application. The Board concurs with the respondent's view that the skilled person, in a contextual reading, would not compartmentalise the teaching of the first original application but would understand that the embodiments of Figures 14 to 17B comprise all the features of the first preferred embodiment of Figures 1 to 13, except where differences are explicitly mentioned or shown. In conclusion, contrary to the appellant's view, the embodiments of Figures 14 to 17B are also in accordance with claim 19 of the first original application and can provide a basis for amendments of claim 19 of the first original application based on additions of their

features.

- 5.4 The appellant also argued that the description of the first original application did not provide a basis for the feature of the at least one pusher member having a base portion configured to reside in the space of the sled and for sliding engagement of the cam wedges, as defined in claim 8 of the patent as granted. According to page 15, line 20, to page 3, line 1, "*pusher member 150a may be configured to reside with [sic] a space 146a between cam wedges 144a*" and "*base 152a of pusher member 150a is configured and adapted for sliding engagement with space 146a of sled 140a*". This passage of the description refers to and should be read together with Figure 17B, and also taking account of Figures 16A and 16B. The way in which the pusher member and the cam wedge of the sled are shown to work in those figures makes it clear that only the base portion of the pusher member resides in a space of the sled, while the pusher member is lifted up. As regards the claimed engagement of the pusher member with the cam wedge, this is not only visible in Figure 17B, but also literally disclosed on page 16, lines 1 to 3.
- 5.5 In conclusion, the subject-matter of claims 1 and 8 of the patent as granted has sufficient basis in the first original application. Hence, Article 76(1) EPC is complied with.
- 5.6 As regards the requirements of Article 123(2) EPC, the subject-matter of claims 1 and 8 of the patent as granted is derived from claims 1 and 8 of the original application and the passages in the description corresponding to those mentioned in relation to the first original application.

5.7 It follows that the ground for opposition according to Article 100(c) EPC does not prejudice the maintenance of the patent as granted.

6. Insufficiency of disclosure

The appellant's objection of insufficiency of disclosure hinges on the interpretation according to which the embodiments of the patent, and in particular those depicted in Figures 16A to 17B, were not in accordance with the invention as defined in claims 1 and 8 of the patent as granted. However, as explained in points 5.1 to 5.3 above, those embodiments are in accordance with those claims. Hence precisely those embodiments provide a sufficient disclosure of the invention as defined in claims 1 and 8 of the patent as granted.

It follows that the ground for opposition according to Article 100(b) EPC does not prejudice the maintenance of the patent as granted.

7. Lack of novelty

The appellant argued that the subject-matter of claim 1 of the patent as granted lacked novelty over A1.

A1 discloses a surgical stapling device. As shown in Figure 1 reproduced below, the device comprises a tool assembly with an anvil (20) and a cartridge assembly (18).

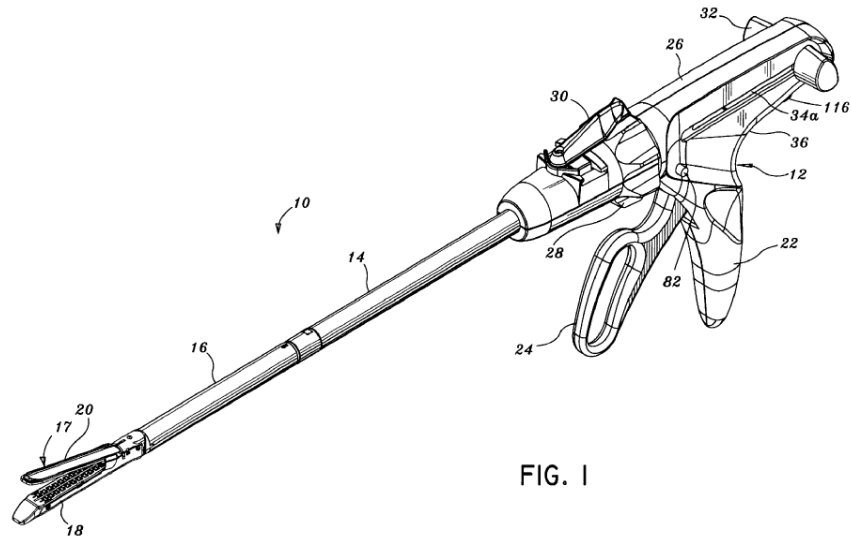


FIG. 1

The tool assembly further comprises a dynamic clamping member provided in a disposable loading unit 16. The dynamic clamping member, which is movable as defined in claim 1, is in the form of axial drive assembly 212, depicted in detail in Figures 31 and 32 reproduced below.

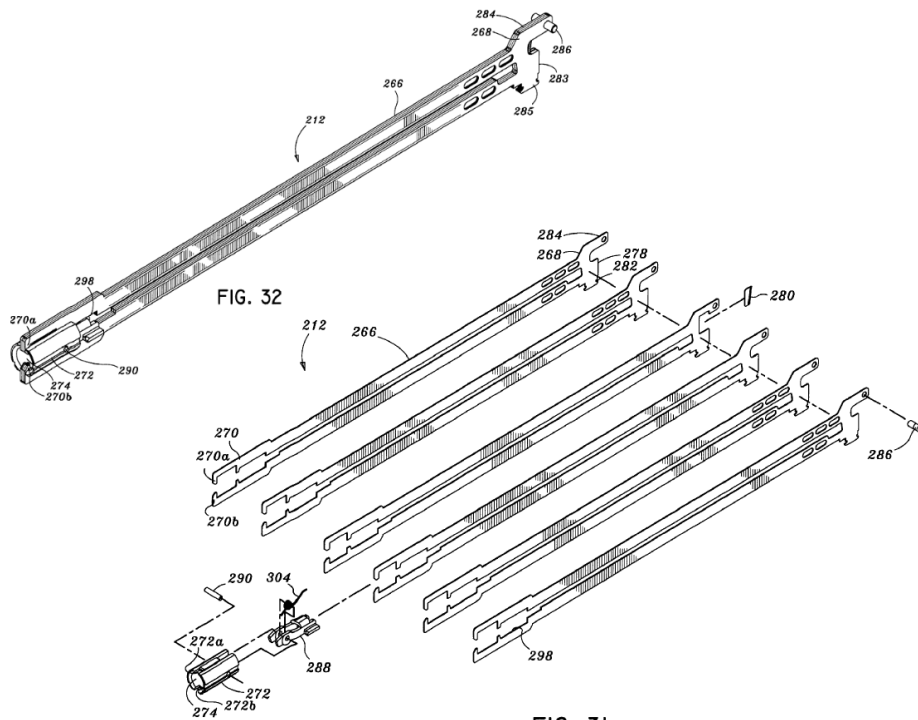


FIG. 31

7.1 According to a first line of argument, the appellant considered axial drive assembly 212 to build up both the clamp member and the dynamic clamping member according to claim 1. However, the claim recites two different members, i.e. two individual elements, on a normal technical interpretation of the claim. The embodiments disclosed in the description and figures of the patent comprise two separate elements. Hence they fully support this normal interpretation. As explained in point 5.2 above, the movement of the clamp member towards its advanced position contributes to the movement of the anvil and the cartridge assembly to the approximated position. Hence, there would be no reason for the skilled person to deviate from the terminology employed in the patent and interpret claim 1 as meaning that both the claimed clamp member and dynamic clamping member were dynamic clamping member 32 of the description and drawings. The appellant's argument that drive assembly 212 of A1 served the same functions as the claimed clamp member and the dynamic clamping member is beside the point in the assessment of novelty since, in general, the same function can be achieved by different structures.

7.2 According to a second line of argument, in view of the fact that axial drive assembly 212 of A1 comprises multiple stacked sheets, the appellant considered the left half of the device assembly to be the clamp member and the right half of the device assembly to be the dynamic clamping member. Even accepting the appellant's interpretation that each sheet of the axial drive assembly could be considered a separate element, the Board notes that those single elements as such could not perform the functions defined in claim 1. Only after assembly, when they were structurally a single

entity, could they perform those claimed functions.

7.3 Hence, the subject-matter of claim 1 is novel over A1, since that document does not disclose a clamp member separate from a dynamic clamping member as claimed.

7.4 It follows that the ground for opposition of lack of novelty according to Article 100(a) EPC does not prejudice the maintenance of the patent as granted.

8. Lack of inventive step

8.1 During the oral proceedings the appellant raised an objection of lack of inventive step of the subject-matter of claims 1 and 8 of the patent as granted starting from A1, in combination with common general knowledge.

This objection amounts to an amendment of the appellant's case, the admission of which is at the Board's discretion under Article 13(1) and (3) RPBA. Such discretion is to be exercised in view of, *inter alia*, the complexity of the new subject-matter submitted, the current state of the proceedings and the need for procedural economy. An amendment should not be admitted if it raises issues with which the Board or the other party cannot reasonably be expected to deal without adjournment of the oral proceedings.

The Board notes that A1 has been on file and held against novelty since the beginning of the appeal proceedings and that the objection of lack of inventive step was raised after the Board's conclusion, in the oral proceedings, that A1 did not deprive the subject-matter of claim 1 of the patent of novelty. Under those circumstances it is reasonable to expect that the other

party and the Board were well acquainted with the technical teaching of A1. Moreover, the objection of lack of inventive step over A1 and common general knowledge focuses on the distinguishing features established by the Board at the conclusion of the novelty discussion. Hence, it does not raise any complex issue that could have a particularly negative impact on procedural economy.

In those circumstances, the Board decides to admit the objection into the proceedings under Article 13(1) and (3) RPBA.

- 8.2 As explained in points 7.1 to 7.3 above, the presence of a clamp member separate from the claimed dynamic clamping member is a distinguishing feature of the subject-matter of claims 1 and 8 over A1.

Both parties referred to paragraph [0030] of the patent, which explained the technical effect of that distinguishing feature. According to that paragraph, utilising the clamp member for pre-clamping the tissue, taken together with the dynamic clamping member that clamps as it translates along the tool assembly, reduces the likelihood that staples are displaced from their intended position during their deformation and maintains the desired tissue gap between the anvil and the cartridge assembly.

The objective technical problem solved is therefore how to more reliably staple together a desired amount of tissue at the desired location.

The generic problem formulated by the appellant (improve clamping) is not accepted, as it ignores the specific effect of the provision of a clamp member

separate from but together with the dynamic clamping member.

The Board accepts the appellant's argument that the provision of a clamp member in a surgical stapling device forms part of common general knowledge in the field. However, neither common general knowledge nor A1 would motivate the skilled person to implement an additional clamp member in the device of A1. A1 simply teaches that clamping is provided by the axial drive assembly 212. It is concerned not with the objective technical problem as formulated above but rather with the provision of a device that can be employed in a variety of procedures (column 2, lines 19 to 27, as pointed out by the respondent).

It follows that the subject-matter of claims 1 and 8 is inventive when starting from A1, in combination with common general knowledge.

8.3 The appellant also argued that the subject-matter of claims 1 and 8 of the patent as granted lacked an inventive step when starting from any of A3, A4, A5 and A6, all of which disclosed surgical staplers.

It is common ground that all of those documents disclose respective clamp members, but none of them discloses, in addition, a dynamic clamping member as defined in claims 1 and 8.

As explained in point 8.2 above, the provision of a clamp member for pre-clamping the tissue, taken together with a dynamic clamping member that clamps as it translates along the tool assembly, reduces the likelihood that staples are displaced from their intended position during their deformation, and

maintains the desired tissue gap between the anvil and the cartridge assembly.

The objective technical problem solved is therefore how to more reliably staple together a desired amount of tissue at the desired location.

The problem formulated by the appellant (maintain a desired tissue gap) is a mere repetition of a technical effect of the dynamic clamping member alone. It does not consider all the claimed elements and their respective effects and interactions to establish what the purpose of the technical effect of the dynamic clamping member might be.

A9 relates to a surgical stapler for performing localised resections of gastro-oesophageal lesions. According to an embodiment referred to by the appellant and depicted in Figures 12 to 15, which are reproduced below, the surgical stapler comprises a dynamic clamping member in the form of an I-beam (70) that is advanced through the stapler, along curved tissue clamping jaws (paragraph [0004] and claim 1) in the form of an anvil (50) and a cartridge assembly (40), in order to cut tissue and fire staples housed in respective staple pushers (118).

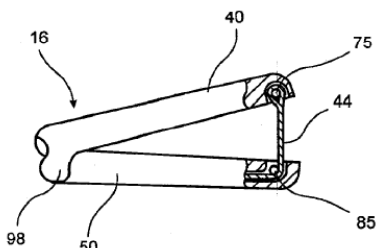


FIG. 12

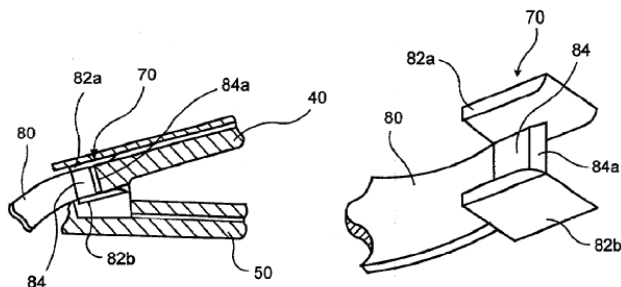


FIG. 13

FIG. 14

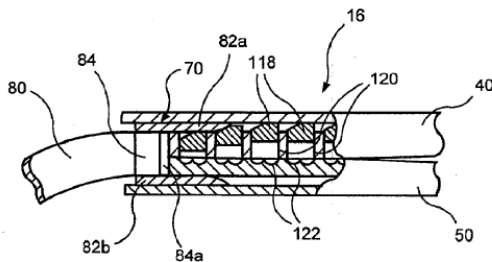


FIG. 15

A9 is not concerned with the objective technical problem. While the appellant argued that the I-beam of A9 was for maintaining a desired tissue gap, A9 neither expressly mentions that a desired tissue gap should be maintained nor teaches any advantage or purpose of such a gap. Hence, the skilled person, faced with the objective technical problem, would have no motivation to carry out all the necessary structural modifications and implement the I-beam of A9 in any of the surgical stapling devices of A3, A4, A5 and A6.

It follows that the appellant's objection of lack of inventive step starting from any of A3, A4, A5 and A6 cannot succeed.

8.4 The appellant also argued that the subject-matter of claims 1 and 8 of the patent as granted lacked an inventive step when starting from A9.

In particular, the appellant argued that A9 further disclosed a clamp member in the form of a cable (44) and that the I-beam (70) had a leading surface that made up a sled within the meaning of claims 1 and 8.

However, as the respondent argued, while each of claims 1 and 8 defines a dynamic clamping member and a sled, the I-beam of A9 is a single component. Moreover, a surface of an element cannot reasonably be interpreted as a sled, within the meaning of claims 1 and 8.

It follows that the subject-matter of claims 1 and 8 differs from the disclosure of A9 in particular in the presence of a sled as a separate component of the tool assembly.

The presence of a sled, separate from the dynamic clamping member, can compensate for possible displacement or deformation of the dynamic clamping member in its movement through the anvil and the cartridge assembly for cutting tissue.

Hence, the Board accepts as the objective technical problem the one formulated by the respondent, i.e. how to provide improved staple alignment.

While the appellant has provided arguments as to why the skilled person would provide a clamp member or staple drive members in the device of A9 based on the teaching of A3, A4, A5 and A11, or A6, it has not provided any arguments as to why the provision of a

separate sled would be obvious in view of the objective technical problem. The Board does also not see any incentive from the cited prior art for the skilled person to implement a further element for ejecting staples in the device of A9.

In conclusion, the subject-matter of claims 1 and 8 is inventive when starting from A9 as the closest prior art.

8.5 It follows that the ground for opposition of lack of inventive step according to Article 100(a) EPC does not prejudice the maintenance of the patent as granted.

9. Since none of the grounds for opposition raised by the appellant prejudices the maintenance of the patent as granted, the Opposition Division's decision to reject the opposition under Article 101(2) EPC was correct.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



D. Hampe

E. Dufrasne

Decision electronically authenticated