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**Datasheet for the decision
of 21 October 2015**

Case Number: T 1534/12 - 3.2.02

Application Number: 07250393.1

Publication Number: 1813211

IPC: A61B17/072, A61B17/28,
A61B19/00

Language of the proceedings: EN

Title of invention:
Surgical fastener and cutter with cable actuator

Patent Proprietor:
Ethicon Endo-Surgery, Inc.

Opponent:
Covidien

Headword:

Relevant legal provisions:
EPC Art. 100(a), 54, 56

Keyword:
Claims - interpretation
Novelty - (yes)
Inventive step - (yes)

Decisions cited:
T 1279/04, T 0012/11

Catchword:



**Beschwerdekammern
Boards of Appeal
Chambres de recours**

European Patent Office
D-80298 MUNICH
GERMANY
Tel. +49 (0) 89 2399-0
Fax +49 (0) 89 2399-4465

Case Number: T 1534/12 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 21 October 2015

Appellant:
(Patent Proprietor)

Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, Ohio 45242 (US)

Representative:

Tunstall, Christopher Stephen
Carpmaels & Ransford LLP
One Southampton Row
London WC1B 5HA (GB)

Respondent:
(Opponent)

Covidien
Suite 8 N-1
Legal Department
555 Long Wharf Drive
New Haven CT 06511 (US)

Representative:

Maschio, Antonio
Maschio & Soames IP Limited
20 Carlton Crescent
Southampton, SO15 2ET (GB)

Decision under appeal:

**Interlocutory decision of the Opposition
Division of the European Patent Office posted on
25 April 2012 concerning the maintenance of
European patent No. 1813211 in amended form.**

Composition of the Board:

Chairman E. Dufrasne
Members: D. Ceccarelli
P. L. P. Weber

Summary of Facts and Submissions

- I. The patent proprietor has appealed the Opposition Division's interlocutory decision, dispatched on 25 April 2012, concerning the maintenance of European patent No. 1 813 211 in amended form according to the then pending third auxiliary request.
- II. The patent was opposed on the grounds of lack of novelty and inventive step.
- III. In its decision, the Opposition Division held that the patent could not be maintained as granted, since the subject-matter of claim 1 lacked novelty over each of the following documents:
- D6: US-A-5,447,513;
D7: US-A-5,954,259.
- IV. The notice of appeal was received on 4 July 2012. The appeal fee was paid on the same day. The statement setting out the grounds for appeal was received on 5 September 2012.
- V. The respondent replied to the statement of grounds by letter dated 14 December 2012. It submitted that the subject-matter of claim 1 of the patent as granted was not novel over each of D6 and D7, and was also not inventive in view inter alia of the following documents:
- D8: US-A-2006/0016853;
D9: US-A-5,667,517;
D11: US-A-2002/0065474.

VI. The Board summoned the parties to oral proceedings and set out its provisional opinion in a communication dated 10 August 2015.

VII. Oral proceedings took place on 21 October 2015.

The appellant requested that the decision under appeal be set aside and that the patent be maintained as granted.

The respondent requested that the appeal be dismissed.

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

"An endoscopic stapling device (10), comprising:

an elongate shaft (12) having proximal (12a) and distal (12b) ends;

an end effector (16) coupled to a distal end of the elongate shaft (12) for engaging tissue and delivering at least one fastener to the engaged tissue;

a handle (14) coupled to a proximal end of the elongate shaft (12); and

an actuator (28) operatively associated with the end effector and the handle,

characterised in that:

the actuator has a first position in which rotation of the actuator is effective to rotate the end effector, and a second position in which rotation of the actuator is effective to fire at least one fastener from the end effector."

Claims 2 to 10 are dependent claims.

IX. The appellant's arguments are summarised as follows:

a) Novelty

In the impugned decision the finding of a lack of novelty of the subject-matter of claim 1 of the patent as granted over D6 centred on an inappropriate interpretation of the following language of the claim: "the actuator has a first position in which rotation of the actuator is effective to rotate the end effector, and a second position in which rotation of the actuator is effective to fire at least one fastener from the end effector".

The only sensible interpretation of this language was that the first position had to mean a position in which rotation of the actuator relative to the claimed device was effective to rotate the end effector relative to the device and that the first and second positions were distinct from one another in that they were different positions of the actuator relative to the device. This was clearly in accordance with the disclosure of the patent as a whole, in particular figure 4 showing the actuator in the first position, figure 6 showing the actuator in the second position, and figures 9A and 9B showing the movement of the actuator from the first to the second position.

D6 did not disclose an actuator having two positions according to this interpretation. It followed that D6 was not novelty-destroying.

D7 did not disclose one and the same actuator which, in a first position, could be rotated to rotate the end effector and, in a second position, could be rotated to fire a fastener. On the contrary, the device disclosed in D7 comprised two different actuators serving entirely different purposes.

It followed that the subject-matter of claim 1 of the patent as granted was novel.

b) Inventive step

Starting from D7 as the closest prior art, the objective technical problem, as described in paragraph [0051] of the patent, was how to provide a device utilising a single actuation mechanism configured to effect both rotation and actuation of the end effector, thereby providing a more convenient and elegant means for controlling orientation and actuation of the end effector. In particular, in the embodiment described in connection with the figures of the patent this was possible by the means of clutch 30 and its interaction with the other elements of the end effector.

D11, relied upon by the respondent, and D7 itself did not address the objective technical problem.

It followed that the subject-matter of claim 1 of the patent as granted was inventive over D7 alone or in combination with D11.

Starting from D8 as the closest prior art, the differentiating feature and the objective

technical problem solved were the same.

D7 and D9, relied upon by the respondent, and D8 itself did not even contemplate the solution of the objective technical problem, since none of them disclosed or even hinted at a device having a single actuation mechanism configured to effect both rotation, when in its first position, and actuation, when in its second position.

It followed that the subject-matter of claim 1 of the patent as granted was inventive over D8 in combination with D7 or D9.

X. The respondent's arguments are summarised as follows:

a) Novelty

As found in the impugned decision, D6 disclosed all the features of claim 1 of the patent as granted. In particular, since the definition of the actuator in the claim was vague and, for example, neither the axes of rotation nor the first and second positions of the actuator were specified, trigger assembly 65 in the figures could be considered as an actuator within the meaning of the claim. As also found in decision T 1279/04, a strict definitional approach to the language of a claim was necessary to ensure legal certainty for third parties. By rotating trigger assembly 65 towards handle 50, a fastener could be fired from jaw member assembly 190 (the end effector within the meaning of the claim) in a first position. Moreover, the whole device of D6, including the trigger assembly, could be rotated about the axis of shaft 20, thereby causing

rotation of the end effector in a second position. In this context, the claim did not even require that the actuator had to move from the first to the second position. The fact that everybody knew that the whole device could be rotated around any axis in space could not exclude, in itself, that such a rotation fell within the meaning of claim 1, and any surgeon using the device of D6 would perform it, if needed.

D7 was even closer to the concept of the embodiment of the patent as described in connection with the figures. It disclosed an endoscopic stapling device according to the definition of claim 1. In particular, the actuator according to the claim was not limited to a single, undivided component. It followed that drive shaft 42, body portion 14 and annular collar 52, which could effect the actuation of both rotation and firing of the apparatus of D7, could be considered as components of a single actuator within the meaning of the claim.

As a result, the subject-matter of claim 1 of the patent as granted lacked novelty over D6 and D7.

b) Inventive step

D7 could be considered the closest prior art. The only possible difference between the subject-matter of claim 1 of the patent as granted and D7 was that, if drive shaft 42 alone was considered the actuator within the meaning of the claim, rotation of this actuator was effective to fire fasteners but not to rotate the end effector. Such a difference was one of intention rather than

structure, since it would be possible to use drive shaft 42 to rotate body portion 14 and thus the end effector, if collar 52 was kept in the position shown in figure 4. This was derivable from column 5, lines 27 to 29 and column 4, lines 51 to 56, explaining that the motor acting on drive shaft 42 could make it rotate in two directions.

The objective technical problem formulated by the appellant was not correct, since the embodiment of the patent described in connection with the figures, intended to fall under the definition of claim 1, did not solve it.

It was apparent from figures 4, 5A and 5B together with column 9, lines 40 to 58 of the patent that when clutch 30, being part of the actuator within the meaning of claim 1, was in the second position, i.e. the position shown in figure 5B, in abutment with ramped surface 20r, the actuator could not rotate to fire a fastener. In other words, the described embodiment did not work as defined by the claim.

Considering the objective technical problem to be the provision of a device which uses a single actuating mechanism for both orienting and firing the end effector, the skilled person would conveniently make use of the motorised mechanism already used to rotate drive shaft 42 of D7. In particular, he would consider D11 from a neighbouring field, relating to a tissue sampling device in which motors were used to selectively drive components of an actuation system, and apply its teaching to the device disclosed in D7,

thereby arriving at the subject-matter of claim 1 in an obvious way.

D8 could also be considered as the closest prior art. The difference between D8 and the subject-matter of claim 1 was that the actuator of D8, in a second position, did not function by rotation but pushed a dynamic clamping member through a cartridge to fire fasteners. The technical effect was that an additional function was achieved using a single type of movement (rotation) of the actuator. In view of this technical effect, the objective technical problem was to modify the stapling device of D8 such that functions of the device were effected by the same type of movement of the actuator. The skilled person would attempt to modify the device of D8 with the expectation that rotational movement of the actuator might be useful to effect firing in addition to orienting the end effector of D8. D9 and D7 taught that rotational movement of a drive rod could be effective to fire staples. The skilled person would apply their teaching to the device of D8, thereby arriving at the subject-matter of claim 1 in an obvious way.

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

Reasons for the Decision

1. The appeal is admissible.

2. *The invention*

The invention as defined in claim 1 of the patent as granted relates to an endoscopic stapling device as generally shown in figure 1A. Such devices are typically used in endoscopic surgery to apply lines of fasteners (staples) on opposing sides of a longitudinal incision in tissue (column 1, lines 21 to 25 and column 12, lines 9 and 10). The fasteners are applied by means of an end effector provided at a distal end of an elongate shaft. The end effector typically comprises two jaws for engaging tissue between them. One jaw comprises a cartridge in which are stored the fasteners to be fired through the engaged tissue, and the other jaw, also commonly called the anvil, is pivotable with respect to the first one. The movements needed to correctly position the end effector and to fire the fasteners are normally controlled at the proximal end of the elongate shaft, which is provided with a handle.

The claimed invention focuses on the provision of an actuator for both rotating the end effector and firing at least one fastener, depending on its "position". More particularly, in a first position, rotation of the actuator is effective to rotate the end effector, while in a second position, rotation of the actuator is effective to fire the at least one fastener.

According to the patent, such an actuator would result in an improved control of the movement and the actuation of the end effector (paragraph [0007]).

3. *Novelty*

In the impugned decision the Opposition Division accepted the respondent's view that both D6 and D7 were

novelty-destroying for the subject-matter of claim 1 of the patent as granted.

- 3.1 D6 discloses an endoscopic surgical instrument for applying a ligating clip to a blood vessel or tissue and which would also be able to cut the blood vessel or tissue without a further instrument having to be inserted (column 2, lines 12 to 17). The surgical instrument is described as being "capable of ligation and division" (column 2, lines 37 and 38). It comprises a proximal handle with an actuator in the form of "trigger assembly 65", actuation of which can "close or form" a clip (column 7, lines 65 to 67). Trigger assembly 65 has a position "in which rotation of the actuator is effective to fire at least one fastener from the end effector" (column 7, lines 46 to 67).

It is disputed by the parties whether the trigger assembly "has a first position in which rotation of the actuator is effective to rotate the end effector" within the meaning of claim 1.

The respondent and the Opposition Division considered that, since in any position it was possible to rotate the trigger assembly with the whole instrument - and thus the end effector - around any axis in order to suitably rotate the end effector, the feature in dispute was disclosed by D6.

In the Board's opinion, however, an interpretation of the wording of the claim such as to include this possibility is not acceptable. It is simply not a reasonable reading of the claim in the present technical context.

While it is agreed with the respondent that, as found

in decision T 1279/04, in examination and opposition proceedings "the value of future legal certainty is paramount", so that the subject-matter of a claim should be interpreted following a "strict definitional approach", this does not allow an artificial reading of the claim fully disconnected from the description and the drawings.

A patent is a technical document concerning an invention in a specific technical field and is written by and directed to persons skilled in that field. As already explained in decision T 12/11 (point 4 of the reasons) by the present Board, the specific vocabulary of a patent, in particular that of the claims, is chosen by a skilled person in the field, i.e. the author, with a precise intention, consistent throughout the patent specification. Therefore, that vocabulary has to be construed from the standpoint of a skilled person reading the specification with a mind desirous to understand that intention. For this purpose the description and the drawings create the context and cast a light on the meaning to be reasonably attributed to the vocabulary employed in the claims. The "strict definitional approach" mentioned in T 1279/04 should take place in this context. Any isolated, artificial, technically meaningless interpretation out of this context is thus to be carefully avoided.

In the present case, a skilled person approaching claim 1 with a mind willing to understand, with due regard to the disclosure of the patent as a whole, would construe the disputed feature as requiring that, when the actuator is in the first position, a rotation of the actuator with respect to other parts of the device causes a rotation of the end effector with respect to those other parts of the device. Moreover,

as the appellant submitted, the differentiation between a "first" and a "second" position of the actuator requires that a movement of the actuator with respect to those other parts of the device takes place if the actuator has to be brought from one of those positions to the other.

The disclosure of the patent as a whole clearly does not support the artificial reading of the respondent and the Opposition Division.

As the appellant submitted, no skilled person would need to describe, let alone claim, the fact that an object as a whole could be rotated around an axis in space. This is clearly known by everybody. Consequently, no skilled person would interpret the feature in claim 1 according to which the actuator has a first position in which rotation of the actuator is effective to rotate the end effector as simply requiring that the actuator together with the whole claimed device - and thus the end effector - could be rotated around any axis in space in order to suitably rotate the end effector. This is simply not what the author was intending to describe.

Moreover, the artificial reading of the respondent and the Opposition Division wrongly assigns no limiting effect to the definition of the "actuator [being] effective to rotate the end effector". During a rotation of the whole device any element defined as "the actuator" would play no role in the rotation of the end effector, but would simply rotate with it. As a result, it could not be considered as an actuator at all.

Therefore, it is concluded that D6 fails to disclose an

actuator having "a first position in which rotation of the actuator is effective to rotate the end effector".

- 3.2 D7 discloses an endoscopic stapling device. Its main elements are visible in figure 1. More particularly, the device of document D7 comprises a trigger (44) for controlling the operation of a motor assembly (22 in figure 2A) which is connected to a drive shaft (42 in figure 2), rotation of which causes fasteners to be fired (column 7, line 56 to column 8, line 5). The device of D7 also discloses a separate rotator mechanism (50) having a collar (52 in figures 2A, 3 and 4), manual rotation of which can rotate cartridge assembly 16 (column 5, lines 30 to 43).

The respondent and the Opposition Division held that drive shaft 42, body portion 14 and collar 52 together formed "the actuator" within the meaning of claim 1 of the patent as granted.

The Board shares the respondent's view that, in principle, an actuator may include a plurality of interlinked elements. However, claim 1 expressly requires that in a first position "rotation of the actuator is effective to rotate the end effector" and in a second position "rotation of the actuator is effective to fire at least one fastener".

In the Board's view, as the appellant also argued, this requires the whole actuator within the meaning of the claim to be capable, in two distinct positions, of performing a rotation with respect to other parts of the device or, at least, one and the same of the interlinked elements forming it should be able to do so.

This is not the case in the device of D7, since to rotate the end effector a rotation of collar 52 with respect to body portion 14 is needed, whereas to fire the fasteners a rotation of drive shaft 42 with respect to body portion 14 is needed.

It follows that D7 fails to disclose the combination of features of the characterising portion of claim 1.

3.3 Consequently, the subject-matter of claim 1 of the patent as granted is novel over the cited prior art.

4. *Inventive step*

4.1 To show that the subject-matter of claim 1 of the patent as granted lacked inventive step, the respondent presented two lines of argument: one starting from D7 as the closest prior art and the other starting from D8.

Like D7, D8 discloses an endoscopic stapling device of the kind defined in claim 1. Its main elements are visible in figure 13A. More particularly, the device of D8 comprises a body portion (18) within which a centre rod (62 in figure 1) can be translated to fire staples (paragraph [0046]) and a coaxial member (60) can be rotated to rotate an end effector (tool assembly 12). D8 discloses several actuators for controlling these two elements (210, 212, 214 in figure 13A as described in paragraph [0048]), but it does not disclose that the latter can be actuated by the rotation of an actuator in two different positions, as required by claim 1.

The Board regards D7 and D8 as equivalent starting points for assessing inventive step. They can both be

considered the closest prior art.

4.2 The subject-matter of claim 1 differs from the disclosure of each of D7 and D8 in that the rotation of the end effector and the firing of the fasteners is performed by rotation of a single actuator, respectively in a first and a second position.

4.3 The technical effect of this differentiating feature is that a single control suffices to perform both actions.

The Board is not convinced by the respondent's argument that from figures 4, 5A and 5B and column 9, lines 40 to 58 of the patent it was not apparent how this effect could be achieved, since in the second position, with ramped surface 20r in abutment with the actuator, the latter could not rotate to fire a fastener.

The patent expressly mentions that its actuator can do that. Moreover, in connection with the description of the preferred embodiment, a part of the actuator responsible for abutting ramped surface 20r is denominated "clutch 30" (column 9, lines 12 to 16, 29 to 32 and 54 to 58). The skilled person would consequently understand that clutch 30, with the actuator in the second position as shown in figure 5B, would act as a clutch, staying in abutment with ramped surface 20r while still permitting a rotation of other parts of the actuator, in particular drive shaft 28 (figure 5B) and gear 32 (figure 6), in order to fire a fastener.

The objective technical problem to be solved, as also derivable from the patent (paragraph [0007]), is therefore how to achieve an improved control of the movement and actuation of an end effector of an

endoscopic stapling device.

The respondent's formulation of the objective technical problem, i.e. how to modify the stapling device of the closest prior art such that functions of the device are effected by the same type of movement of the actuator, is not accepted, since it contains pointers to the solution: it presupposes the presence of a single actuator for performing both movements as expressly claimed. In accordance with the established jurisprudence of the boards of appeal (as cited in Case Law of the Boards of Appeal, 7th edition 2013, I.D.4.3.1), the Board is of the opinion that such a formulation of the objective technical problem results in an inappropriate, ex post facto analysis of inventive step.

- 4.4 None of the documents relied upon by the respondent discloses an endoscopic stapling device with which the rotation of the end effector and the firing of the fasteners is performed by rotation of a single actuator, respectively in two positions.

The respondent argued that with the device of D7 it would be possible to use drive shaft 42 to rotate body portion 14 and thus the end effector, if collar 52 was kept in the position shown in figure 4. The Board, however, is not convinced that this is the case. D7 neither expressly mentions nor implicitly foresees such a use of the drive shaft. It does not describe how a rotation of drive shaft 42 could be transmitted to body portion 14 so as to perform a controlled orientation of the end effector. On the contrary, it is clearly foreseen that drive shaft 42 rotates within body portion 14 while the latter remains stationary (column 5, lines 27 to 29).

The respondent further argued that D11 disclosed that motors could be used to selectively drive components of an actuation system, and taught use of the rotary movement of drive shaft 42 of D7 to also orientate the end effector. However, D11 relates to a tissue sampling device comprising a sampling needle, used in particular in breast tissue biopsy procedures (paragraph [0001]). D11 has simply nothing to do with the problem to be solved, so that there is no reason for the skilled person to consider this document. There is no doubt that, generally, a single motor/actuator can be used for performing different actions. This general concept is known to the skilled person. There is however no apparent reason why the skilled person would apply it to an endoscopic stapling device like the one disclosed in D7 without any specific hint in that direction.

Starting from D8 as the closest prior art, the respondent argued that D7 and D9 disclosed that staples could be fired by conversion of a rotary movement and that the skilled person would implement this rotary movement to control the translation of centre rod 62 of D8. However, the Board fails to see any reason why the skilled person, in view of the problem to be solved, would extract only this rotary movement from the whole disclosure of D7 or D9 and implement it to control the translation of centre rod 62 of D8, such that firing of the staples could be controlled by a rotary movement of a single actuator. Even if wanting to use an electric drive motor to fire the staples, as argued by the respondent, the skilled person would most probably consider two different actuators for two different rotary motions, as also generally contemplated in D8, paragraph [0048]. Moreover, applying the mentioned feature of D7 and D9 to the

device of D8 would require considerable mechanical modifications.

For these reasons the Board concludes that the subject-matter of claim 1 of the patent as granted is inventive over the cited prior art.

5. It follows that the grounds according to Article 100(a) EPC on which the respondent based its opposition do not prejudice the maintenance of the European patent as granted.

Order

For these reasons it is decided that:

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

The Registrar:

The Chairman:



D. Hampe

E. Dufrasne

Decision electronically authenticated