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**Datasheet for the decision  
of 7 May 2019**

**Case Number:** T 0170/14 - 3.2.02

**Application Number:** 07250382.4

**Publication Number:** 1813207

**IPC:** A61B17/072

**Language of the proceedings:** EN

**Title of invention:**

Surgical Instrument with electronic safety-interlocks

**Patent Proprietor:**

ETHICON ENDO-SURGERY, INC.

**Opponent:**

Covidien

**Headword:**

**Relevant legal provisions:**

EPC Art. 56, 100(a)

**Keyword:**

Inventive step - main request (no) - auxiliary request (yes)

**Decisions cited:**

G 0007/95

**Catchword:**



**Beschwerdekammern**

**Boards of Appeal**

**Chambres de recours**

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Case Number: T 0170/14 - 3.2.02

**D E C I S I O N**  
**of Technical Board of Appeal 3.2.02**  
**of 7 May 2019**

**Appellant:** Covidien  
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**Decision under appeal:** **Decision of the Opposition Division of the  
European Patent Office posted on 15 November  
2013 rejecting the opposition filed against  
European patent No. 1813207 pursuant to Article  
101(2) EPC.**

**Composition of the Board:**

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

## **Summary of Facts and Submissions**

- I. The opponent's appeal is against the Opposition Division's decision dated 15 November 2013 to reject the opposition.

Notice of appeal was filed on 14 January 2014. The appeal fee was paid on the same day. The statement setting out the grounds of appeal was filed on 21 March 2014.

- II. Oral proceedings were held on 7 May 2019.

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

The respondent/patent proprietor 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 and 2 filed with letter dated 6 August 2014.

The appellant/opponent withdrew its request for the ground for opposition of lack of novelty to be introduced into the appeal proceedings.

- III. The following documents are cited in the decision:

D1: US-A-5693042  
D3: US-A-5667517  
D5: US-A-2002/049454

- IV. Claim 1 of the patent as granted (main request) reads as follows:

"A surgical cutting and stapling instrument (10) comprising:

an end effector (12) comprising:

a channel (22);

an anvil (24) pivotally attached (25) to the channel;

a moveable cutting instrument (32) for cutting an object positioned between the anvil and the channel;

and

a staple cartridge (34) configured for removable receipt by the channel, wherein the staple cartridge comprises a sled (33) that is engaged by the cutting instrument during a cutting stroke and;

a handle (6) comprising a motor (65) for actuating the cutting instrument via a main drive shaft assembly (36, 48, 50, 68, 70, 72, 74, 78, 80, 122, 124) and

a first interlock circuit (137) for enabling initiation of motor operation based upon a position of the staple cartridge;

characterized by:

a second interlock circuit (142, 306) for preventing pivotal movement of the anvil relative to the channel during movement of the cutting instrument."

V. Claim 1 according to auxiliary request 1 reads as follows:

"A surgical cutting and stapling instrument (10) comprising:

an end effector (12) comprising:

a channel (22);

an anvil (24) pivotally attached to the channel;

a moveable cutting instrument (32) for cutting an object positioned between the anvil and the channel;

and

a staple cartridge (34) configured for removable receipt by the channel, wherein the staple cartridge comprises a sled (33) that is engaged by the cutting instrument during a cutting stroke and;  
a handle (6) comprising a motor (65) for actuating the cutting instrument via a main drive shaft assembly and a first interlock circuit (137) for enabling initiation of motor operation based upon a position of the staple cartridge;

characterized by:

a second interlock circuit for preventing pivotal movement of the anvil relative to the channel during movement of the cutting instrument, wherein the second interlock circuit comprises an electromechanical actuator (306, 308) configured to prevent opening of the anvil relative to the channel during movement of the cutting instrument."

VI. The appellant/opponent's arguments relevant for the decision and not endorsed by the Board can be summarised as follows:

Main request - novelty

The subject-matter of claim 1 was anticipated by both D3 and D5. In D3 the sensor 87 had to be considered a part of an interlock circuit as claimed.

Auxiliary request 1 - inventive step

In D5, the motor 76 used to clamp and unclamp the tissue was also an electromechanical actuator and therefore anticipated the above additional feature, or at least suggested the feature of claim 1 as an obvious alternative.

VII. The respondent/patent proprietor's arguments relevant for the decision can be summarised as follows:

Main request - novelty

Pursuant to G7/95 (OJ EPO 1996, 626), the respondent/patent proprietor considered that the only document which could be used for a lack of novelty objection under the ground for opposition of lack of inventive step was the closest prior art.

Main request - inventive step

D1 did not directly and unambiguously disclose that the motor was in the handle, since the only information in this respect was that electrical energy communication means comprising wires 18 entered the instrument through the handle.

Starting from D1, the objective problem was one of improving the device in general so that the person skilled in the art would not necessarily take over a feature concerning the clamping procedure.

The operating program described in D5 was specifically conceived for a circular surgical stapler, so the person skilled in the art had no incentive to solve the objective technical problem of a linear surgical stapler by incorporating this feature.

### **Reasons for the Decision**

1. The appeal is admissible.
2. The invention

The invention concerns a linear surgical cutting and stapling instrument with two jaws. The handle of the instrument comprises a first trigger 18 for closing the jaws and a second trigger 20 for firing, i.e. advancing the sled, firing the staples and cutting. An electrical safety feature (second interlock circuit) prevents jaws being opened as long as the sled is travelling. The closure trigger 18 is retained in its closed position and cannot be freed (solenenoid 306 with plunger 308 in Figures 14 and 15).

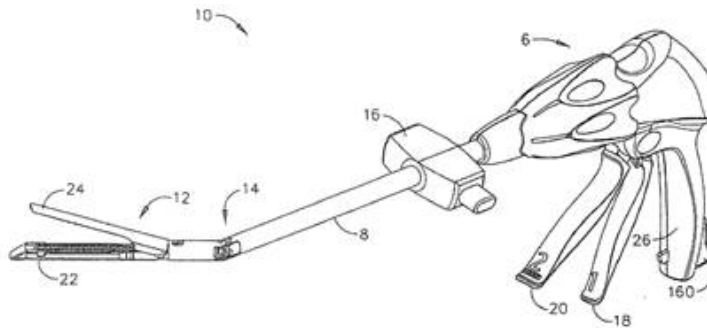


FIG. 2

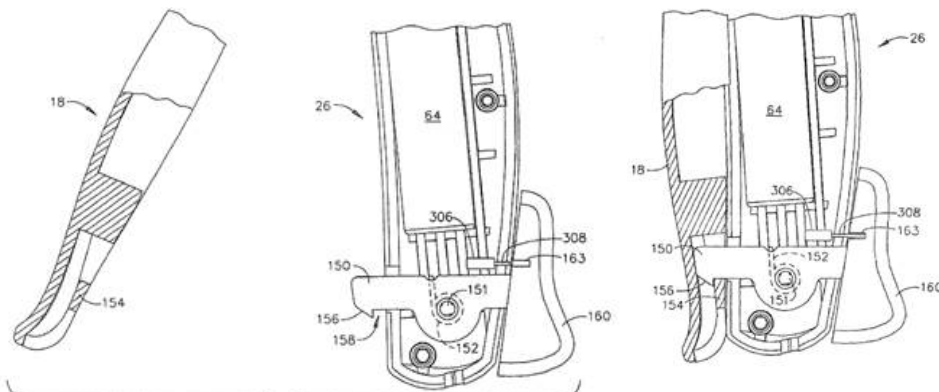


FIG. 14

FIG. 15

3. Main request - novelty



The appellant/opponent considered that both D3 and D5 anticipated the subject-matter of claim 1.

The only ground for opposition present in the notice of opposition and used in the opposition proceedings was lack of inventive step. Pursuant to G 7/95 (OJ EPO 1996, 626), the respondent/patent proprietor considered that the only document which could be used for a lack of novelty objection under the ground for opposition of lack of inventive step was the closest prior art as mentioned in the above decision.

In decision G 7/95, the Enlarged Board of Appeal decided that: *"In a case where a patent has been opposed under Article 100(a) EPC on the ground that the claims lack an inventive step in view of documents cited in the notice of opposition, the ground of lack of novelty based upon Articles 52(1), 54 EPC is a fresh ground for opposition and accordingly may not be introduced into the appeal proceedings without the agreement of the patentee. However, the allegation that the claims lack novelty in view of the closest prior art document may be considered in the context of deciding upon the ground of lack of inventive step."*

More explicitly, in the reasons for the decision the following was stated:

*"7.2 Nevertheless, in a case such as that under consideration in the decision of referral in case G 7/95, if the closest prior art document destroys the novelty of the claimed subject-matter, such subject-matter obviously cannot involve an inventive step. Therefore, a finding of lack of novelty in such circumstances inevitably results in such subject-matter*

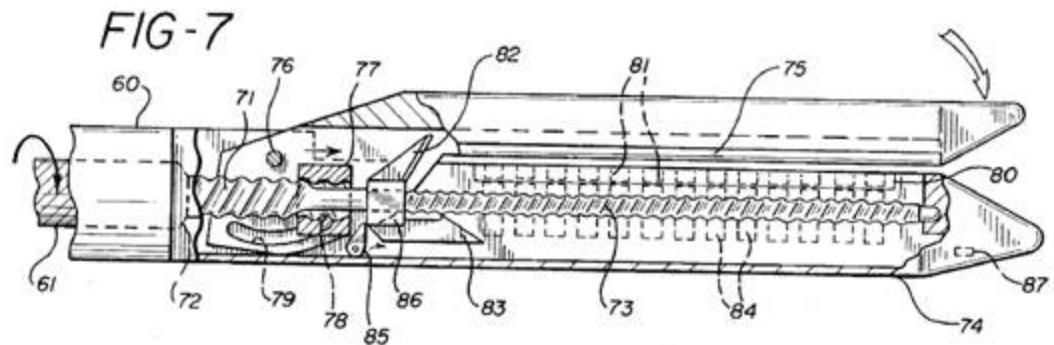
*being unallowable on the ground of lack of inventive step."*

The Enlarged Board considered only the case of the closest prior art destroying novelty; other documents were not mentioned. In the Board's opinion, however, it would seem odd not to apply this principle to other documents, since other such documents could always be used in a discussion of lack of inventive step, so lack of novelty in view of D3 or D5 could be examined in the present case under the ground for opposition of lack of inventive step.

Claim 1 requires the motor to be in the handle. This is precisely what D5 wishes to abandon ([0011] and [0014]): "*[0014] It is therefore an object of the present invention to provide an electro-mechanical surgical device, in which a motor system is provided remote from the surgical instrument.*" Therefore, the stapler according to D5 does not include the motor in the handle.

In the stapler according to D3, there is (at least) no interlock circuit for preventing pivotal movement of the anvil relative to the channel during movement of the cutting instrument. The mechanical switch 85 seen in Figures 6 to 10 cannot be compared to a circuit. In this device, by reason of the presence of a thread on it, the rotation of the drive shaft 61 moves the nut 77 to close the jaws. At the end of its travel it leaves the larger-diameter threading 71 and knocks the switch 85 to push the cutting member 82, 83, 86 into engagement with the smaller-diameter threading 73. This way of functioning is purely mechanical. Contrary to the appellant/opponent's opinion, the sensor 87 meant to detect the distal end position of the knife member

82, 83 cannot be considered a part of an interlock circuit since its role is limited to reversing the motor such that the knife member is drawn back to its initial position. This sensor has no further function.



Moreover, it is noted that in D3 there is no positive means preventing opening of the anvil jaw apart from the closure nut 77 and, while sensors are presented, it is not mentioned that the sensors will lead to any blocking whatsoever of any element. On the contrary, it is explained, for instance in column 6, lines 40 to 47, that the surgeon will receive the information, which implies that it is the surgeon who will decide what to do with it, not the control unit.

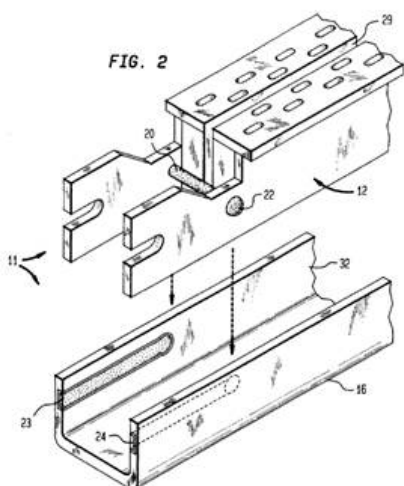
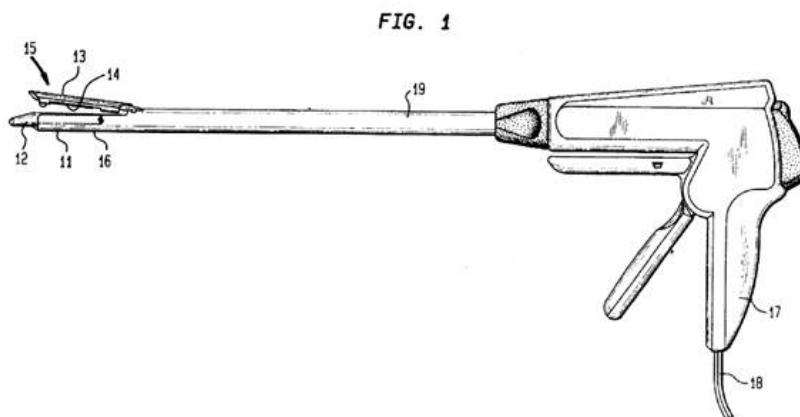
Therefore, the subject-matter of claim 1 is novel in view of D3 and D5.

4. Main request - inventive step

4.1 The appellant/opponent considered that D1 was the closest prior art and that the subject-matter of claim 1 was obvious in view of D5.

D1 discloses a linear-jaw surgical stapler including an electrical circuit linked to the staple cartridge able to detect the cartridge type or status (with or without

staples). According to column 3, lines 13 to 30: "If the cartridge is inappropriate or the staples have been fired, then instrument use is locked out with a lock-out means..."



The respondent/patent proprietor alleged that it was not directly and unambiguously disclosed that the motor was in the handle, since the only information in this respect was that electrical energy communication means comprising wires 18 enter the instrument through the handle (column 4, lines, 49 to 53), which would be insufficient to demonstrate that the motor was in the handle.

The Board does not share this view. If wires are stated as entering the handle to provide electrical energy, implicitly this energy will be used inside the handle. The document does not refer to the wires for providing information from sensors, which would be a different situation. Moreover, if the motor were outside the handle, wires would be insufficient to fire the instrument; instead, a rotating drive shaft or some other drive means would have to enter the handle, as is well known in the art. Therefore, in the Board's opinion, it is unambiguously disclosed for the person skilled in the art that the motor is in the handle.

Both parties accept that the other features of the first part of claim 1 are disclosed in D1, and the Board has no doubt either.

- 4.2 Therefore, the differentiating feature is the characterising feature that a second interlock circuit for preventing pivotal movement of the anvil relative to the channel during movement of the cutting instrument is present in the instrument.
- 4.3 The technical effect of that differentiating feature can be deemed to be preventing an unacceptable cutting and stapling operation or preventing possible mechanical damage to the instrument, since it is ensured that the anvil jaw will not open until the cutting and stapling operation is finished and the cutting instrument is back in its initial position.
- 4.4 The objective problem can therefore be considered to be one of improving the cutting and stapling procedure, in particular preventing an unfinished operation. This problem is a daily concern for the person skilled in the art since it is self-evident that uncompleted

cutting and suturing is to be avoided for the patient's benefit.

- 4.5 The embodiments of the invention presented in the description of the patent use a solenoid 306 with a plunger 308 to mechanically prevent any possible displacement of the release button 160 or release mechanism, i.e. there is a means positively hindering the actuation of the release button or mechanism meant to release the closure trigger 18.

The Board notes that the wording of the differentiating feature is more general and encompasses, for instance, the case of a sensor not being activated and not allowing electrical current to flow to a jaw-driving motor.

This is exactly what is rendered obvious by D5.

D5 discloses a surgical apparatus comprising a remote power console 12 and a flexible shaft 20 (incorporating drive shafts), at the distal end 24 of which a coupling 26 makes it possible to connect several kinds of surgical instruments or attachments, in particular a linear surgical stapler-cutter or a circular stapler-cutter (paragraph [0048]).

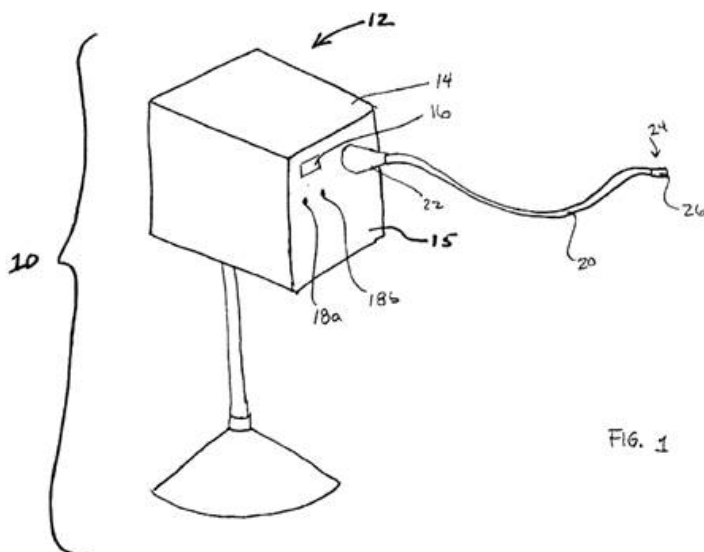


FIG. 1

The device according to D5 is provided with sensors for determining the relative position of the components, and with operating programs corresponding to the electro-mechanical surgical devices to be attached thereto (paragraphs [0016] and [0017]). The main embodiment described in D5 is when a circular surgical stapler-cutter is attached to the distal end of the flexible drive shaft.

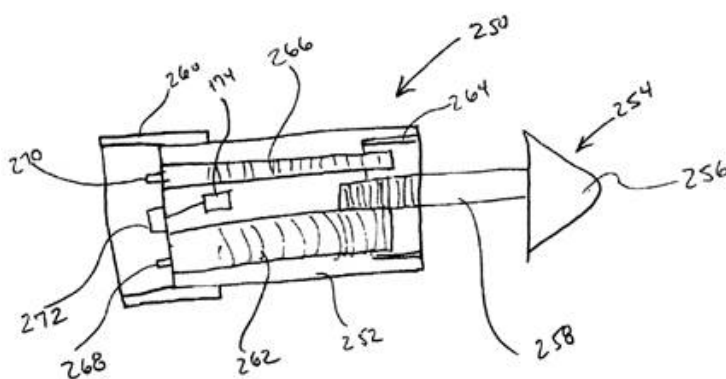


FIG. 9A

As explained in paragraph [0062], "in the example circular surgical stapler attachment 250 shown in FIG. 9a, the extension and retraction of the anvil 256 is

*effected by the operation of the first motor 76, and the extension and retraction of the staple driver/cutter 264 is effected by the operation of the second motor 80."*

As further explained in the document, in particular in paragraph [0074], the anvil 256 is moved by the first motor 76 until the gap between the anvil 256 and the body portion 252 is determined to be within an acceptable range indicating that the tissue is clamped therebetween. When this condition is fulfilled the first motor is stopped and the firing function (which was disabled up to then) is enabled, which in turn allows the staple driver/cutter to be moved by the second motor 80.

Once the stapling/cutting operation is finished the second motor 80 will retract the staple driver/cutter 264, as explained in particular in paragraph [0096]: *"After it is determined that the retraction of staple driver/cutter 264 has been completed (step 1152) or that the predetermined time limit has been exceeded (step 1148), the unclamp motor current limit is set of full scale in step 1154. In this context, the unclamp motor may correspond to first motor 76 as more fully described hereinabove."*

In other words, in this embodiment the unclamp motor 76 is not activated until the staple driver/cutter is back in its initial position. This means that the clamp/unclamp motor 76 is prevented from unclamping the tissue, i.e. separating the jaws (anvil and body portion) during movement of the staple driver/cutter. This procedure clearly avoids premature unclamping, which brings with it the risk of some tissue parts along the cutting edges still being somehow attached to



the cutting tool, which would be detrimental to the surgical operation being completed cleanly and safely.

In the Board's opinion the person skilled in the art would take this interlock circuit over into the device according to D1 to solve the objective problem and thereby arrive at the subject-matter of claim 1 without the exercise of any inventive step.

- 4.6 The respondent/patent proprietor considered that the objective problem was one of improving the device in general so that the person skilled in the art would not necessarily take over a feature concerning the clamping procedure. Moreover, the operating program described in D5 was specifically conceived for a circular surgical stapler, so the person skilled in the art had no incentive to solve the objective technical problem of a linear surgical stapler by incorporating this feature.

The Board does not share this opinion. The characterising portion of claim 1 is a feature concerning the clamping/cutting/stapling procedure. As already expressed above, it is self-evident that this clamping/cutting/stapling procedure is the very reason why these devices exist. This surgical procedure is the most important feature of such a device since it directly influences the surgical result for the patient, which is what ultimately must be successfully performed. Features as regards where the motor is positioned, how the housing is constructed, which sensor is placed where, etc. are of secondary importance in this respect. This is why improvement of the clamping/cutting/stapling procedure is always of central importance for the person skilled in the art.

It is true that the operating program disclosed in D5 is described in relation to a circular surgical stapler, but it is clear from the document, in particular from paragraph [0048], that the teaching of the document is applicable to a number of instruments or attachments. While the Board accepts that the described operating program is not directly applicable to e.g. a surgical clip ligator, a vessel expanding device or a scalpel also mentioned in the list of possible attachments, the Board considers that it is directly applicable to a linear surgical stapler because the steps to be performed in both kinds of stapler are similar, if not to some extent identical: the tissue is clamped between two jaws, the tissue is cut and stapled, the jaws are opened to free the clamped tissue. The teaching of D5 is that the clamping/unclamping motor should be prevented (by appropriate sensors) from being activated while the cutting step takes place. This teaching is directly applicable to a linear surgical stapler when using a motor for the clamping/unclamping step as it is in any case obvious to use in the electromechanical linear stapler disclosed in D1.

- 4.7 For the above reasons, the subject-matter of claim 1 of the main request is not inventive.

Hence, the ground for opposition of lack of inventive step pursuant to Article 100(a) EPC prejudices the maintenance of the patent as granted.

5. Auxiliary request 1 - inventive step

- 5.1 The characterising portion of claim 1 of auxiliary request 1 reads as follows:

*"a second interlock circuit (142, 306) for preventing pivotal movement of the anvil relative to the channel during movement of the cutting instrument, wherein the second interlock circuit comprises an electromechanical actuator (306, 308) configured to prevent opening of the anvil relative to the channel during movement of the cutting instrument."*

In other words, this feature requires the second interlock circuit to comprise an electromechanical actuator which is specifically configured to prevent the opening of the anvil.

- 5.2 The characterising portion as a whole remains the differentiating feature over the disclosure according to D1 since D1 does not disclose any such electromechanical actuator.
- 5.3 The technical effect of the additional feature is that it allows opening of the anvil to be positively prevented as opposed to passively as allowed for by the wording of the characterising portion of claim 1 according to the main request. Moreover, requiring an actuator specifically configured for that function increases safety because a malfunction in the electrical circuit for energising the opening and closing motor of the anvil will not influence the desired prevention.
- 5.4 The objective problem remains the same as well.
- 5.5 In the Board's opinion, the subject-matter of claim 1 is inventive starting from D1 as closest prior art and in combination with D5. Although, as explained above, D5 uses sensors to detect the position of the anvil allowing the unclamping motor to be activated, it does

not suggest the use of a separate electromechanical actuator specifically configured to prevent opening of the anvil during the movement of the cutting instrument.

- 5.6 The appellant/opponent alleged that the motor 76 used to clamp and unclamp the tissue in D5 was also an electromechanical actuator and therefore anticipated the above additional feature, or at least suggested the feature of claim 1 as an obvious alternative to it.

The Board does not share this opinion. In the device according to D5, as explained above, the motor 76 is activated to move the anvil only when moving the anvil is desired, and not when this movement is not desired. The motor is not specifically configured to prevent the opening of the anvil during the movement of the cutting instrument. Therefore, the teaching of D5 in that respect cannot lead the person skilled in the art to the subject-matter of claim 1.

- 5.7 For the reasons above, the subject-matter of claim 1 according to the auxiliary request 1 is inventive pursuant to Article 56 EPC.

Hence, the ground for opposition of lack of inventive step pursuant to Article 100(a) EPC does not prejudice the maintenance of the patent according to auxiliary request 1.

6. Neither the appellant/opponent nor the Board had any objection to the adapted description.

## Order

### For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the department of first instance, with the order to maintain the patent on the basis of:
  - claims 1 to 8 of auxiliary request 1 filed with letter dated 6 August 2014;
  - description: columns 1, 2 and 5 to 28 of the patent as granted, and columns 3 and 4 filed during the oral proceedings; and
  - Figures 1 to 44c of the patent as granted.

The Registrar:

The Chairman:



D. Hampe

E. Dufrasne

Decision electronically authenticated