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**Datasheet for the decision
of 6 July 2017**

Case Number: T 2115/15 - 3.2.02

Application Number: 10012264.7

Publication Number: 2311393

IPC: A61B17/32, B25B23/142

Language of the proceedings: EN

Title of invention:
Instrument for cutting tissue

Patent Proprietor:
Covidien LP

Opponent:
ETHICON ENDO-SURGERY, INC.

Headword:

Relevant legal provisions:
EPC Art. 113(1), 76(1)
EPC R. 111(2), 103(1)(a)

Keyword:

Right to be heard - opportunity to comment (yes)
Appealed decision - reasoned (yes) - substantial procedural
violation (no)
Reimbursement of appeal fee - (no)
Divisional application - added subject-matter (yes)

Decisions cited:

G 0003/89, G 0011/91, G 0002/10

Catchword:



Beschwerdekammern
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Case Number: T 2115/15 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 6 July 2017

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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on
8 September 2015 revoking European patent
No. 2311393 pursuant to Article 101(3) (b) EPC.**

Composition of the Board:

Chairman E. Dufrasne
Members: D. Ceccarelli
M. Stern

Summary of Facts and Submissions

- I. The patent proprietor has appealed the Opposition Division's decision, dispatched on 8 September 2015, to revoke European patent No. 2 311 393.
- II. The Opposition Division held that none of the requests on file complied with Article 76(1) EPC, since their respective claim 1 introduced subject-matter extending beyond the content of the first parent application as filed.
- III. The notice of appeal was received on 6 November 2015. The appeal fee was paid on the same day. The statement setting out the grounds of appeal was received on 15 January 2016.
- IV. Oral proceedings took place on 6 July 2017.

The appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of one of the main request, first and second auxiliary requests, all filed with letter dated 15 January 2016. It further requested that the appeal fee be reimbursed due to a substantial procedural violation in the impugned decision, and that the case be remitted to the Opposition Division for further prosecution on issues of novelty and inventive step.

The respondent requested that the appeal be dismissed.

- V. Claim 1 of the main request reads as follows:

"An ultrasonic instrument (212;412), comprising:
a housing (222;422) having a proximal end, the housing having a stationary handle (228;424);

a movable handle (236;436) pivotally connected to the housing (222;422);
an ultrasonic transducer (230;430;630) attachable to the housing (222;422) so that the ultrasonic transducer (230;430;630) is supported within and extends from the proximal end of housing (222;422);
an elongate body portion (224;424) extending distally from the housing (222;422);
a jaw assembly (232;432) disposed at a distal end of the elongate body portion (224;424), the jaw assembly (232;432) having a clamp (260;460) that is moved by movement of the movable handle (236;436), the jaw assembly (232;432) including a cutting jaw (258;458);
a vibration coupler (250;450) including a distal end (256) and a proximal end (252;452) configured to operatively engage the ultrasonic transducer (230;430;630)

characterized in that the cutting jaw (258;458) is integral with the distal end (256) of the vibration coupler (250;450), and the elongate body portion (224;424), clamp (260;460), cutting jaw (258;458), housing (222;422), stationary handle (228;428) and movable handle (236;436) being packaged as an integral unit requiring no assembly by the user prior to use."

VI. Claim 1 of the first auxiliary request has the same preamble as claim 1 of the main request. Its characterising portion reads:

"the cutting jaw (258;458) is formed integrally with the distal end (256) of the vibration coupler (250;450), and the elongate body portion (224;424), clamp (260;460), cutting jaw (258;458), housing (222;422), stationary handle (228;428) and movable handle (236;436) being packaged as an integral unit

requiring no assembly by the user prior to use."

- VII. Claim 1 of the second auxiliary request has the same preamble as claim 1 of the main request. Its characterising portion reads:

"the cutting jaw (258;458) is integral with the distal end (256) of the vibration coupler (250;450), and the elongate body portion (224;424), clamp (260;460), cutting jaw (258;458), housing (222;422), stationary handle (228;428) and movable handle (236;436) being packaged as an integral unit requiring no assembly by the user prior to use further comprising a torque wrench assembly (670) configured and dimensioned to engage the ultrasonic transducer (630)."

- VIII. The appellant's arguments may be summarised as follows:

Substantial procedural violation

The impugned decision was tainted by a substantial procedural violation for two reasons: it was based on an objection which had not been made before, so that the appellant had not been given the opportunity to comment on it, and, to the extent that it referred to issues commented upon by the appellant, it was not reasoned.

More particularly, in the first sentence of paragraph 30 the Opposition Division provided a reasoned objection why the combination of an integral blade and an integral packaging as defined in claim 1 of the main request constituted added subject-matter. This objection had, however, not been made before in the opposition proceedings.

In paragraphs 27 and 31 the Opposition Division alleged that the scope of the claims had shifted from a claim focusing on a construction of a clamp and a blade to an embodiment comprising an integral jaw and an integral packaging. However, no adequately reasoned objection was based upon this allegation.

Added subject-matter

The invention as defined in claim 1 of all requests concerned a surgical stapler. According to the original disclosure, the stapler possessed two features: an angled blade and the fact that it could be packaged as an integral unit.

The integral packaging feature was clearly not concerned with the same problem as the angled blade. As a solution to a different problem, the integral packaging feature could be claimed separately. There was no reason why the skilled person would conclude that it could only be claimed together with the angled blade.

More particularly, the application as filed comprised multiple embodiments. One embodiment, described at paragraphs [0010] to [0025], related to the angled blade. This embodiment was not described as being packaged as an integral unit. A second and a third embodiment, described at paragraphs [0026] to [0037] and [0038] to [0052] respectively, concerned a particular transducer arrangement, which allowed packaging of the instrument as an integral unit. Paragraph [0034], which included the statement "*the user needs only to attach transducer 230 to housing 222 to ready the instrument 212 for use*" represented an implicit description of a problem and its solution,

i.e. the provision of a one-piece instrument for facilitating its set-up before use. There was no relationship between this problem and solution, and the feature of the angled blade. Although the angled blade was also described in the context of the second and third embodiments, in particular in paragraph [0030]), its presence had to be considered as not essential in those embodiments. In this respect, the present case differed from other case law, in which the removal of a feature from an originally-disclosed combination was not allowed because the combination as a whole addressed a single technical problem.

For these reasons claim 1 of all requests did not introduce any technical subject-matter which the skilled person would not derive directly and unambiguously, using common general knowledge from the first parent application as originally filed, in accordance with the "gold" standard referred to in G 2/10.

IX. The respondent's arguments may be summarised as follows:

Substantial procedural violation

The impugned decision, in particular paragraph 30, clearly explained that it was the claimed combination of an undisclosed selection of features to solve an undisclosed problem that contravened Article 76(1) EPC. Paragraphs 31 and 32 correctly pointed out that, as a result, the scope of protection of the granted patent had shifted compared with the application as filed. This matter had been addressed in particular in the notice of opposition dated 17 January 2014 and had formed the basis of the discussion during the oral

proceedings before the Opposition Division, as could be seen from section 3.2 of the minutes. Hence, the appellant had been given the opportunity to comment on the ground, reasoned in the decision, which had led to the revocation of the patent.

Added subject-matter

The original application focused on the provision of an angled blade for a surgical stapler. The angled blade was consistently presented as the essence of the invention from the very first paragraph of the original disclosure, throughout the whole detailed description of the embodiments, and in all independent claims. In particular, the embodiments described at paragraphs [0026] to [0037] and [0038] to [0052] also clearly comprised an angled blade. The disclosure that several elements of the staplers according to those embodiments could be packaged as an integral unit was presented in a single sentence, still within the specific context of an instrument with an angled blade. For example, paragraph [0030] explained the details and advantages of such a blade within that context. In other words, that sentence simply disclosed how the instrument with the angled blade according to the original invention could be suitably packaged.

By drafting claim 1 of all requests without defining the angled blade the skilled person was presented with the technical teaching, not disclosed in the original application, that the angled blade was unnecessary.

This technical teaching was not directly and unambiguously derivable from the original application. It followed that all requests contravened Article 76(1) EPC.

Reasons for the Decision

1. The appeal is admissible.
2. The invention

The invention as defined in claim 1 of all requests relates to an ultrasonic instrument, for example as depicted in figure 12 of the patent, reproduced below.

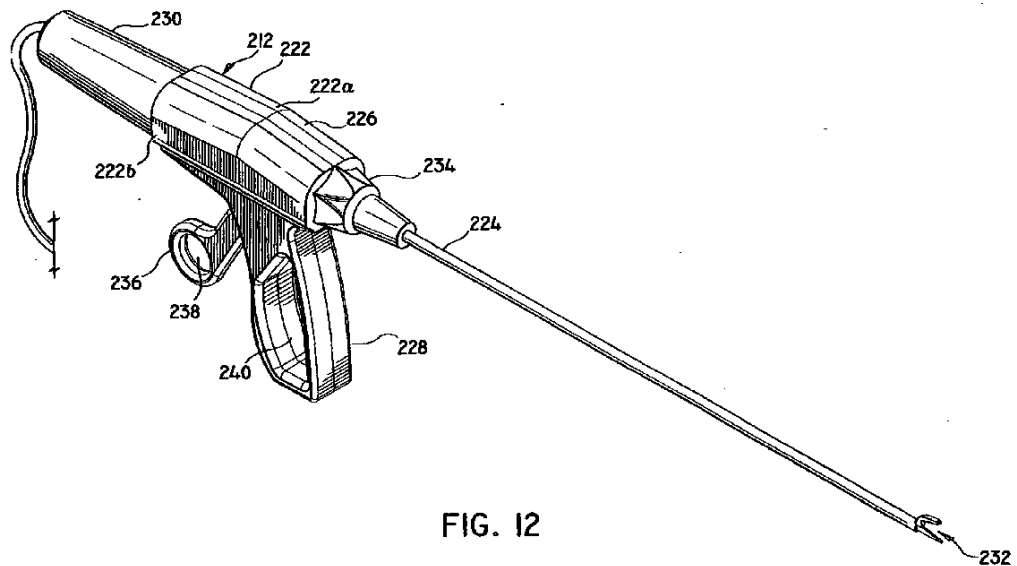


FIG. 12

The instrument has a housing (222) supporting an ultrasonic transducer (230), a stationary (228) and a movable (236) handle for manipulating a jaw assembly (232) disposed at a distal end of an elongate body portion (224) extending from the housing. The jaw assembly comprises a cutting jaw and a clamp.

Such ultrasonic instruments are typically used in surgery for performing dissection and coagulation of tissue. More particularly, the elongate body portion

may be introduced into a patient's body through a trocar, so that it reaches the tissue to be dissected (for example a blood vessel). The tissue is then clamped and cut by the cutting jaw by manipulation of the handles and the actuation of the ultrasonic transducer.

The features of the characterising portion of claim 1 of all requests relate to the cutting jaw being defined as integral with the distal end of the vibration coupler, and the elongate body portion, the clamp, the cutting jaw, the housing, the stationary handle and the movable handle being packaged as an integral unit requiring no assembly by the user prior to use.

From the patent it is derivable that these features facilitate the use of the instrument, since the user only needs to attach the transducer to the housing to have the instrument ready for use.

3. The patent is derived from divisional application No. 10012264.7 (published as EP-A-2 311 393) of application number 08008175.5, which is itself a divisional of 06010587.1, which is itself a divisional of 97944573.1 (hereinafter "the first parent").

It is common ground that the technical disclosure of the first parent application as originally filed is also present in all those divisional applications as originally filed. For the purpose of assessing compliance with Article 76(1) EPC it is therefore sufficient to consider the first parent application as originally filed.

For ease of citation the (numbered) paragraphs of the description of the present application as published,

which correspond to respective (not numbered) paragraphs of the description of the first parent application as originally filed, will be referred to.

4. *Substantial procedural violation*

The appellant argued that the impugned decision was tainted by a substantial procedural violation.

The Board notes that the paragraphs of the impugned decision specifically dealing with the ground for the revocation of the patent are 22 to 32.

In paragraph 26 it is explained that "*in the original application the subjective technical problem is presented as being the improvement of the cutting results by providing good blade to tissue contact*" and that "*this problem is solved by providing a particular combination between a clamp member and an angled blade member*".

Paragraph 27 goes on to say that "*the claimed subject-matter is shifted from the particular combination between the clamp member and the blade member discussed originally to a particular construction of the cutting jaw and vibration coupler and the packaging of parts as an integral unit in order to avoid assembly by the user prior to use*".

It is clear from paragraph 31 that the Opposition Division considered this shift as problematic in view of Article 76(1) EPC: "*the granted patent has now a different scope of protection than it could be foreseen, shifting from an ultrasonic instrument with a particular construction of a clamp and blade member in order to achieve better cutting properties to an*

ultrasonic instrument in which particular parts are such constructed or packaged to assure less assembly prior to use". In the light of this statement, the following sentences provide the reasons why, in the Opposition Division's opinion, this shift contravened Article 76(1) EPC. In particular: "by reading the original application the skilled person could not have foreseen that such an invention would be granted".

Paragraph 30 can only be read in this context. This makes clear that the first sentence of that paragraph provides additional reasons why the Opposition Division concluded that the shift was in contravention of Article 76(1) EPC: *"the combination of the two features above [i.e. the claimed construction of the cutting jaw and vibration coupler, and packaging of parts as an integral unit in order to avoid assembly by the user prior to use] was not presented as solving a particular problem and it was no indication in the original application [...] that such a combination of features would be pursued".*

In summary, the Opposition Division provided sufficient reasons in its decision as to why it concluded that the above-mentioned shift in the claimed subject-matter did not comply with Article 76(1) EPC. Hence, Rule 111(2) EPC is complied with.

The appellant may argue that these reasons are wrong. However, this is a substantive rather than a procedural issue, and one which plays no role in the assessment of whether a decision has been adequately reasoned.

The Board also notes that the issue of the shift in the claimed subject-matter was presented by the respondent in the notice of opposition. In Part II - Formal

Grounds of Opposition, section C, entitled "Art.100(c) - *Shift in claimed invention against the interests of third parties*", it is specifically argued (paragraphs 12 and 13) that "*the opposed patent was granted to the patentee with claims which have nothing to do with the invention set out in the original application and which could not have been foreseen*", and that "*there is nothing in the first application [...] which explains that [...] the packaging of parts as an integral unit] was not also entirely conventional; addressed a perceived problem; or was a concept for which the patentee intended to pursue protection*". The requirements of Article 76(1) EPC in general and the particular issue of the shift in the claimed subject-matter were also discussed in the oral proceedings at first instance, as derivable from section 3 of the minutes. In particular, in section 3.2 mentioned by the respondent it is stated: "*the patent proprietor argues that a third party reading the entire earlier application would realise that it contains subject-matter for solving technical problems other than the one solved by the original claim features. Hence, a third party could have reasonably expected that this subject-matter may be claimed in a divisional application*".

For these reasons the Board concludes that the appellant was not deprived of its right to be heard on the ground and arguments on which the revocation of the patent was based. Hence, Article 113(1) EPC is complied with.

As a consequence, no substantial procedural violation was committed by the Opposition Division. It follows that the appellant's request for reimbursement of the

appeal fee is refused under Rule 103(1)(a) EPC.

5. *Added subject-matter*

- 5.1 The respondent argued that omitting the definition of an angled blade in claim 1 of all requests contravened Article 76(1) EPC.

In this respect, Article 76(1) EPC is only complied with if the information provided by this omission is directly and unambiguously derivable by the skilled person, using common general knowledge and seen objectively and relative to the date of filing of the first parent application, from the whole of this application as originally filed. This is the general test for assessing added subject-matter established in opinion G 3/89 and decision G 11/91, and referred to as the "gold" standard in decision G 2/10 (point 4.3 of the Reasons).

- 5.2 Paragraph [0001] of the description of the application as published reads:

"The present disclosure relates to an ultrasonic dissection and coagulation system for surgical use. More specifically, the present disclosure relates to an ultrasonic instrument including an angled blade and a clamp member particularly suited for performing dissection and coagulation of tissue."

In the section "Background of Related Art" (paragraph [0004]) the only explicitly defined "need" to be satisfied by the invention is presented as follows:

"Accordingly, a need exists for an improved ultrasonic surgical instrument which is easy to use and provides fast and easy cutting and improved coagulation."

The "SUMMARY" of the invention goes on to explain how this need is satisfied, in particular by the angled blade. According to paragraph [0005], last sentence, and paragraph [0006], last sentence:

"The clamp member and angled blade member combine to enhance contact between the tissue and the blade member during operation of the instrument to improve the performance of the instrument."

"Because the cutting blade is angled with respect to the longitudinal axis of the elongated body portion, the contact pressure applied by the blade surface is increased as the force applied of the instrument is increased."

Consistently, all the preferred embodiments presented in the detailed description and all the independent claims of the first parent application as filed comprised an angled blade.

5.3 It is the Board's view that the skilled person, considering the whole of the disclosure of the first parent application as originally filed, would grasp the technical teaching that the angled blade is an important feature of the described ultrasonic surgical instrument.

In this context, the appellant's argument that the features of the characterising portion of claim 1 of all the requests are not concerned with the same

problem as the angled blade is not decisive. The Board acknowledges that the problems addressed are different. More particularly, from the description of the embodiments in paragraphs [0026] to [0037] and [0038] to [0052] of the present application as published, referred to by the appellant, the problem of facilitating the set-up of the ultrasonic instrument before use, solved by the claimed provision of a one-piece instrument, is derivable. However, that same description also includes a detailed disclosure of the angled blade and its advantages (for example in paragraphs [0030] and [0042]).

In the Board's view, the teaching of those embodiments is that, in the general context of the ultrasonic instrument with the specific angled blade as consistently described throughout the first parent application as originally filed, the provision of a one-piece instrument as claimed may be a further advantage. This alone, however, is not sufficient for concluding that the skilled person would directly and unambiguously derive, using common general knowledge and seen objectively and relative to the date of filing of the first parent application, that the angled blade can be dispensed with.

For these reasons, claim 1 of all the requests, conveying the information that the angled blade is merely an optional feature of the ultrasonic instrument disclosed in the patent, introduces subject-matter which extends beyond the content of the first parent application as originally filed. It follows that Article 76(1) EPC is not complied with.

6. Since none of the requests is found to comply with Article 76(1) EPC the appellant's request that the case

be remitted to the Opposition Division for further prosecution on issues of novelty and inventive step is without object.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



D. Hampe

E. Dufrasne

Decision electronically authenticated