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DECISION of 19 September 2002

Case Number:	T 0591/02 - 3.2.2			
Application Number:	98204209.5			
Publication Number:	0913125			
IPC:	A61B 17/32			

Language of the proceedings: EN

Title of invention: Ultrasonics scalpel blade and methods of application

Applicant:

ETHICON ENDO-SURGERY, INC.

Opponent:

Headword:

Relevant legal provisions: EPC Art. 52(1), 56, 84

Keyword:
"Inventive step (yes, after amendment)"
"Clarity (yes)"

Decisions cited:

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Catchword:

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Boards of Appeal

Chambres de recours

Case Number: T 0591/02 - 3.2.2

D E C I S I O N of the Technical Board of Appeal 3.2.2 of 19 September 2002

Appellant:	ETHICON ENDO-SURGERY, INC.			
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	Cincinnati, OH 45242-2839	(US)		

Representative:	Mercer, Christopher Paul			
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Decision under appeal: Decision of the Examining Division of the European Patent Office posted 9 January 2002 refusing European patent application No. 98 204 209.5 pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman:	W.	D.	Wei	ß	
Members:	s.	s.	Chowdhury		
	J.	s.	Μ.	De	Preter

Summary of Facts and Submissions

I. This appeal is against the decision of the examining division dated 9 January 2002 to refuse European patent application No. 98 204 209.5.

The ground of refusal was that, having regard to DE-A-4 040 537 ("D1"), the subject-matter of claim 1 lacked inventive step.

The examining division argued that claim 1 related to a surgical tool in which the objective problem was to improve the multi-functionality of the tool known from document D1. This problem was explicitly addressed in D1 and it would be obvious to add to the tool of Figure 45C of D1 a further sharpened side edge opposite to the edge having the hook-shaped recess. Moreover, the person skilled in the art would, by mere trial and error, select a rectilinearly extending non-sharpened end surface as the shape which performs best for a given situation. The examining division also noted clarity objections.

- II. On 15 March 2002 the appellant (applicant) lodged an appeal against the decision, having paid the prescribed fee on the previous day. On 16 May 2002 a statement of grounds of appeal was filed.
- III. Following a telephone consultation between the appellant's representative and the rapporteur the appellant filed new claims and description pages. Further minor amendment was agreed in the description.
- IV. The appellant requests that the decision under appeal be set aside and that a patent be granted on the basis

of the following documents:

- Claims 1 to 8 filed by letter dated 10 September 2002
- Description pages 1 to 4 and 6 to 16 filed by letter dated 10 September 2002 with the amendments agreed on 17 September 2002.
- Description page 5 as originally filed
- Drawing Figures 1 to 10 as originally filed.

V. Independent claim 1 reads as follows:

"An ultrasonic scalpel blade (50) comprising a blade coupler (49) having a blade body (54) and a shank (52) extending from said blade body (54) for coupling with a source of ultrasonic energy and transmitting the energy to said blade body (54), said body (54) having substantially straight opposing side edges (56, 58) and a tip (60) opposite said shank (52), one of said side edges (56) having a recess (62) formed therein comprising a sharpened edge and defining a hook portion between said one side edge (56) and said tip (60) for tensioning tissue as the blade (50) is displaced along the tissue, thereby facilitating cutting and coagulation of the tissue upon application of ultrasonic energy to the tissue, characterised in that the side edge (58) opposite said one side edge (56) includes an elongated sharpened edge and in that said tip (60) has a flat, rectilinearly extending nonsharpened end surface extending between said opposite side edges (56, 58)".

Claims 2 to 8 are dependent on claim 1.

VI. The appellant argued as follows:

The general teaching of document D1 was that the scalpel blades used should be designed for only one purpose, whereas the present invention provided a significant advantage that there was no need to remove the scalpel blade since one blade would perform all the required procedures of cutting, pulling, pushing, separating, coagulating, and hemostasis of tissue. The blades shown in Figure 46 had at most two functions, but in each case there was a sharp blade tip, which taught away from the invention.

Reason for the Decision

1. The appeal is admissible since it complies with the provisions mentioned in Rule 65(1) EPC.

2. Amendments

Original claim 1 has been amplified by the addition at the end of the claim of the words "and in that said tip has a flat, rectilinearly extending non-sharpened end surface extending between said opposite side edges".

These features are supported by column 8, lines 38 to 43 and Figures 7 to 9 of the A2 publication. Dependent claims 2 to 5 correspond to claims 3 to 6 as originally filed, dependent claim 6 corresponds to claim 8 as originally filed, claim 7 is supported by column 9, lines 32 and 33 of the A2 publication, and dependent claim 8 corresponds to claim 9 as originally filed.

The description has been amended for consistency with the new claims. Therefore, there is no objection to the claims or the description under Art 123(2) EPC.

3. Clarity

The examining division noted that while the opening passages of the original description stress that the invention employs dull blades in contrast to the sharp blades of the prior art, this feature was absent from claim 1.

This omission is justified for the following reasons:

Originally, two different inventions were disclosed, one with reference to Figures 1 to 5, in which a dull blade is employed, and the second with reference to Figures 6 to 10, which concentrates on maximising the coupling of ultrasonic energy to tissue to be coagulated, see point 5.2 below. The application now claims only the second invention and there is no contradiction between claim 1 and the amended description. The second paragraph of the original description, which mentioned the benefits of dull blades, has been cancelled since it is no longer relevant to the claimed invention.

4. Novelty

This has not been an issue during the examination procedure and the Board sees no reason to question the novelty of the claimed apparatus.

5. Inventive step

5.1 Closest prior art

The examining division and the appellant are in agreement that document D1 describes the closest prior

art since the ultrasonic scalpel blade described with reference to Figure 45C discloses an ultrasonic scalpel blade corresponding to the preamble of claim 1, a finding with which the Board concurs.

This document does not disclose the characterising features of claim 1.

5.2 The technical problem

Based on this difference the examining division defined the objective problem as being to improve the multifunctionality of the ultrasonic scalpel blade known from document D1. This problem is defined too broadly and does not take into consideration the true achievement of the claimed device over the prior art. Were the claimed device simply to add another known capability to the blade of document D1, for example the ability to pierce tissue by means of a pointed end, then the resulting device would simply comprise a collocation of known features, in the manner of a Swiss Army knife. However, this is not the case here.

It was found by the inventors that a sharpened blade is less effective for coagulation than a relatively dull blade, and in the extreme, a flat tip is particularly useful for providing exceptional coagulation for bleeders (column 2, lines 27 to 36 and column 8, lines 25 to 33 of the A2 publication). A flat rectilinear end surface is provided at the tip of the ultrasonic scalpel blade in order to provide for this ability of the blade, accordingly.

Therefore, the problem was to enhance the coagulation properties of the known ultrasonic scalpel blade to the

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extent that it was capable of providing exceptional haemostasis.

- 5.3 This by itself is indicative of inventive activity since the prior art does not teach extending the functional capabilities of a scalpel blade from a mixed function (cutting with simultaneous coagulation) to a purely non-manipulative function (coagulation only). That is to say the present scalpel blade may be used in a cutting and coagulation mode via a side edge of the blade, and subsequently in a purely coagulation mode via application of ultrasonic energy at the flat tip of the blade, without any accompanying cutting action. The latter mode of use enables the ultrasonic scalpel blade to provide exceptional haemostasis.
- 5.4 There is no support for the examining division's assertion, particularly in the absence of documentary evidence, that the person skilled in the art would, by mere trial and error, select a rectilinearly extending non-sharpened end surface as the shape which performs best for a given situation.

In particular, there is no evidence in the prior art of the application of a flat end surface of a probe for attaining exceptional coagulation for bleeders, whose advantages are set out in column 2, lines 27 to 36.

5.5 The prior art discloses ultrasonic scalpel blades either with an edge or point at the tip for cutting or piercing tissue, or otherwise with a rounded tip so as to avoid injury to the tissue. These variants are shown in Figures 45 and 46 of document D1. In view of this a flat tip at the end of a generally rectilinear configuration of the blade would not readily suggest

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itself to the person skilled in the art.

6. For the above reasons the scalpel blade of claim 1 involves an inventive step and the application meets the requirements of the EPC.

Order

For these reasons it is decided:

1. The decision under appeal is set aside.

2. The case is remitted to the first instance to grant a patent on the basis of the main request according to paragraph IV. of the "Summary of Facts and Submissions".

The Registrar:

The Chairman:

V. Commare

W. D. Weiß