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Datasheet for the decision of 17 June 2010

Case Number: T 1683/07 - 3.2.02

Application Number: 97950985.8

Publication Number: 1006898

IPC: A61B 17/32

Language of the proceedings: EN

Title of invention:
Surgical instrument

Patentee:
SMITH & NEPHEW, INC.

Opponent:
Gebr. Brasseler GmbH & Co. KG

Headword:
-

Relevant legal provisions:
EPC Art. 54(1),(2), 56, 83, 123(2)

Relevant legal provisions (EPC 1973):
-

Keyword:
"Sufficiency of disclosure (yes)"
"Extended subject-matter (no)"
"Novelty (yes)"
"Inventive step (yes)"

Decisions cited:
T 0204/83

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 1683/07 **-** 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 17 June 2010

Appellant: (Opponent)
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Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 11 July 2007 rejecting the opposition filed against European patent No. 1006898 pursuant to Article 102(2) EPC 1973.

Composition of the Board:

Chairman: M. Noël
Members: C. Körber
M. J. Vogel
P. L. P. Weber
A. Pignatelli

Summary of Facts and Submissions

I. By its decision posted on 11 July 2007 the Opposition Division rejected the opposition against European patent No. 1006898 on the grounds of added subject-matter, insufficient disclosure and lack of novelty and inventive step.

II. An appeal was lodged against this decision by the appellant (opponent), by notice received on 12 September 2007, with the appeal fee being paid on the same day. The statement setting out the grounds of appeal was received on 12 November 2007. The counter-statement of the respondent (patentee) was received on 16 May 2008.

III. By communication of 23 March 2010, the Board forwarded its provisional opinion to the parties.

IV. Oral proceedings were held on 17 June 2010, at the end of which the appellant requested that the decision under appeal be set aside and that the European patent be revoked. The respondent requested that the appeal be dismissed and that the patent be maintained as granted (main request) or in amended form on the basis of one of the auxiliary requests 1 to 6 filed on 17 May 2010.

V. The following documents are of importance for the present decision:

D2: DE 29616633 U1;
D3: US-A-5 437 630;
D6: US-A-5 489 291;
D8: DE 8313370 U1;

D9: Brochure "Perfekt in Funktion und Design", pages 1 to 8, Fa. FRIATEC AG, 4th Quarter 1994;
D10: Technical drawing No. ARO1-611040 9774 of Fa. EBERLE dated 7 March 1992;
D11: Technical drawing No. ARO1-611040-FI of Fa. EBERLE dated 9 January 1992;
Dl2: Order ("Auftrag") No. MC 041645 of Fa. FRIATEC AG dated 9 September 1994, pages 1 to 3;
Dl3: Delivery voucher ("Lieferschein") of Fa. EBERLE KG to Fa. FRIATEC AG dated 13 July 1994.

VI. Claim 1 of the patent as granted (main request) reads:

"A surgical instrument comprising an outer tube (12) having an opening (20) at a distal end thereof, an inner tube (14) disposed for rotation within said outer tube, said inner tube having an interior passage between a distal end and a proximal end thereof, and a surgical tool (16) including a proximal shank (19) mounted to said distal end of said inner tube and a fluted tissue cutting burr (18) disposed distally of said shank and positioned within said outer tube opening, **characterized in that** said shank including a wall (28) that defines an interior chamber (30) in communication with said passage, said wall including an aperture (26) therein that intersects said chamber for conveying tissue fragments cut by said burr into said chamber and thence into said passage, said aperture having a width which is at least one-half of an outer diameter of said wall or approximately one-half of said diameter of said wall."

VII. The arguments of the appellant may be summarised as follows:

In feature K of claim 1 (see feature breakdown presented in point 2 below), reference was made to the "diameter of said wall". However, a wall could only have a thickness but not a diameter. A diameter could in principle only be attributed to the shank 19, but this was also not possible due to the conicity of the shank. Moreover, the definitions in options A and B were contradictory in that the term "approximately" in option B comprised values lower than one-half of the diameter which was excluded in the range according to option A. Consequently, the skilled person was not provided with sufficient information with regard to the width of the aperture.

The definition in option A of feature K in claim 1 was not comprised in the application documents as originally filed. At page 2, lines 20 to 21 it was merely disclosed that the width of the aperture was greater than one-half of the diameter of the wall, but this was not a sufficient basis for the definition "**at least** one-half of an **outer** diameter ..." according to option A. Moreover, option B was mentioned subsequently in feature K and thus had to be regarded as a further limitation and not as an alternative. Accordingly, feature K extended beyond the content of the original disclosure.

Document D2 was novelty-destroying for claim 1. In addition to features A to E, a proximal shank as defined in feature F was disclosed distally of the vertical line (extending normal to the longitudinal axis of the surgical tool) shown proximal of the aperture 16 in Figure 1. This vertical line represented a juncture ("Fügestelle") between the shank of the tool and the inner tube, as also stated in the second paragraph of

page 6 ("verbunden"). The wall of this shank defined an inner chamber and comprised an aperture 16 intersecting therewith, as defined in features H to J. Moreover, it was clearly evident from Figure 1 that said aperture had a width of approximately one-half of the diameter of the wall, as defined in option B of feature K. The width of the aperture 16 and the outer diameter of the shaft could also be measured in Figure 1 by means of a ruler.

The features of claim 1 were also anticipated through prior use as documented by D9 to D13. The conical portion adjacent to the inner tube shown in D10 and D11 represented a proximal shank according to feature F, exhibiting a chamber and an aperture as defined in features H to J. The width of the aperture and the outer diameter of the shaft could be measured from the technical drawing D11 and fell within the range defined in option A of feature K. If necessary, it was proposed to hear again the witness Mr. Amann with respect to the ordering, production and delivery of the surgical instrument forming the subject of the prior use.

D2 as closest prior art aimed at achieving high tissue-removal rates. It was clear to the skilled person that this was not possible when the apertures were clogged. Accordingly, the problem of enhancing the efficiency at which tissue fragments were aspirated as mentioned in the patent in suit was known from D2. This problem was already solved by the large apertures disclosed in D2. Moreover, D3, D6 and D8 also disclosed apertures having a width falling within the range defined in feature K of claim 1. Furthermore, the subject of the prior use clearly comprised an aperture of such width, as measurable from the technical drawing D11. Manufacturing

procedures and material properties of the various parts of the surgical instrument were of no relevance when solving the above-mentioned problem, and anyhow considered to be well within the general knowledge of the skilled person. Furthermore, feature F was comprised in the preamble of claim 1, and as such regarded as known from the closest prior art. Consequently, the subject-matter of claim 1 did not involve an inventive step.

VIII. The arguments of the respondent may be summarised as follows:

The appellant's objection of insufficiency of disclosure was not convincing since it was clear that the wall was used to make up the shank, and that the outer diameter of the wall was also the outer diameter of the shank. The shank itself was tubular and thus had a constant and well-defined diameter. Options A and B in feature K of claim 1 were clearly presented as alternatives and therefore neither unclear nor contradictory.

The basis for feature K could be found in paragraph [0028] of the patent specification (corresponding to the second paragraph of page 9 of the description as originally filed).

D2 failed to disclose a separate shank piece. Furthermore, the size of the three apertures could not be derived from the schematic drawing shown in Figure 1.

Since the shank shown in D10 and D11 was clearly solid and the aperture was located in the inner tube, the

subject of the prior use was irrelevant and not novelty-destroying.

The problem underlying feature K was to enhance the efficiency at which large tissue fragments severed by the burr were aspirated through the inner tube. By means of a separate shank as defined in feature F it was possible to use different, specifically adapted materials for the burr and its shank on the one hand and the inner tube on the other hand. Neither D2 nor D9 to D13 gave a hint towards these advantages. In D2, large particles were already avoided by the specific design of the burr producing only small fragments, and the problem of clogging of the apertures was not considered. In D3, D6 and D8 the apertures were located in the burr itself, and their size could not be derived from these disclosures. Moreover, the working principle of the instruments disclosed in these documents was entirely different from that of D2. Accordingly, when starting from D2, none of these documents rendered obvious the subject-matter of claim 1.

Reasons for the Decision

1. The appeal is admissible.

2. The following feature breakdown of claim 1 as granted, proposed by the appellant with its statement of grounds of appeal, is used by the Board for the present decision:

A. A surgical instrument comprising

B. an outer tube (12) having an opening (20) at a distal end thereof,

C. an inner tube (14) disposed for rotation within said outer tube,

D. said inner tube having an interior passage between a distal end and a proximal end thereof, and

E. a surgical tool (16) including

F. a proximal shank (19) mounted to said distal end of said inner tube and

G. a fluted tissue cutting burr (18) disposed distally of said shank and positioned within said outer tube opening,

H. said shank including a wall (28) that defines an interior chamber (30) in communication with said passage,

I. said wall including an aperture (26) therein

J. that intersects said chamber for conveying tissue fragments cut by said burr into said chamber and thence into said passage,

K. said aperture having a width which is at least one-half of an outer diameter of said wall [option A] or approximately one-half of said diameter of said wall [option B].

3. Sufficiency of disclosure

Feature K of claim 1 refers to the "outer diameter of said wall". Although a wall does not per se have a diameter, for the reader it is clear from feature H, interpreted in the light of the description as a whole and the drawings, that the wall makes up the shank, and that the term "outer diameter of said wall" actually refers to the outer diameter of the shank formed by the wall.

The shank 19 is explicitly denoted as "tubular" in lines 1 to 2 of column 2 and line 44 of column 3, and shown as a cylindrical part in the drawings. Accordingly, the shank has a constant and thus clearly defined outer diameter. The fact that the shank 19 is connected to the burr 18 by means of a tapered neck 25 does not imply that the shank itself is conical and that its diameter is thus ill-defined, contrary to the appellant's assertion.

Feature K defines two possible widths of the aperture, viz. option A ("at least one-half") or option B ("approximately one-half"). These options are not to be seen as mutually exclusive and may overlap. The use of the term "approximately" in option B is to be understood as including fabrication tolerances in the usual technical sense. Accordingly, widths of the aperture which are substantially smaller than one-half of the outer diameter are not to be covered by option B, and consequently there is no contradiction with option A, contrary to the appellant's assertion. The skilled person is provided with sufficient information to put the invention into practice according to either one of these options.

From the above it follows that the invention is disclosed in a manner sufficiently clear and complete within the meaning of Article 83 EPC.

4. Amendments

Claim 1 is based on original claims 1 to 3. The latter defines that the width (w) of the aperture 26 is greater than one-half of the outer diameter (d) of the wall 28 of the shank ($w > 1/2\ d$), whereas option A of feature K is somewhat broader in that it defines a width which is at least one-half of the outer diameter of said wall ($w \geq 1/2\ d$). This slightly extended range is disclosed at page 9, lines 10 to 12 of the original description as published (WO-A-98/27876). The subsequent sentence makes it explicitly clear that the **outer** diameter of wall 28 is meant.

The fact that lines 20 to 21 of page 2 merely refer to the definition given in original claim 3 is of no relevance since the above-mentioned passage at page 9 of the detailed description provides a clear basis for the amendment. The appellant's argument regarding the sequence of the mentioning of the two options in feature K, i.e. first option A and thereafter option B, implying that the latter is to be regarded as a limitation of the former, is not justified since both options are clearly presented as equal alternatives ("or") without any preference.

Accordingly, claim 1 as granted does not comprise added subject-matter and is in accordance with the requirements of Article 123(2) EPC.

5. Novelty

5.1 Document D2

Document D2 undisputedly discloses (Figure 1) a surgical instrument comprising features A to E and G of claim 1 in suit. The surgical tool 12 is integral with the distal end of the inner tube 14 (see page 6, second paragraph). However, feature F requires that a proximal shank of the surgical tool is mounted to the distal end of the inner tube, i.e. separate therefrom. The vertical line (extending normal to the longitudinal axis) shown proximal of the apertures 16 in Figure 1 cannot be taken as indicating a juncture ("Fügestelle") between a shank of the tool, located distally of this line, and the inner tube 14, located proximally thereof. The description of D2 does not refer to this line and does not mention any such juncture. The fact that in the second paragraph of page 6 it is stated that the **inner tube** 14 comprises three apertures, which are located distally of this line as can be seen from Figure 1, is a clear indication that the inner tube 14 also extends distally of this line, without any juncture.

Since D2 does not anticipate a shank within the meaning of feature F, it also fails to disclose that said shank includes a wall defining an interior chamber and having an aperture therein intersecting said chamber as required by subsequent features H, I and J. In the second paragraph of page 6 it is expressly stated that apertures 16 are located in the **inner tube** ("Schafthülse 14").

Furthermore, the description of D2 is entirely silent with respect to the width of the apertures 16 (feature K). In the second paragraph of page 6 it is merely stated that three apertures 16 are distributed evenly about the circumference of the distal part of the inner tube 14. This statement does not allow any conclusions regarding the size or width of these apertures. The fact that it is possible to arrange three apertures dimensioned according to option B around the circumference of the shank, as argued in the decision under appeal (page 10, second paragraph), does not imply that the claimed relationship is anticipated. The Board also does not share the view of the appellant that it is "clearly evident" from Figure 1 of D2 that the apertures have a width which is approximately one-half of the diameter of the wall, as defined in option B of feature K. As indicated above, the term "approximately" does not imply a large bandwidth or variation, but is to be understood as including fabrication tolerances. Finally, it is not permissible to derive specific dimensions from an entirely schematic drawing (T 204/83), as attempted by the appellant with respect to Figure 1 of D2.

From the above it follows that the subject-matter of claim 1 is distinguished over the disclosure of D2 by features F and H to K. Its subject-matter is therefore new with respect to D2.

5.2 Prior use D9 to D13

The Board considers that the subject of the prior use and its availability to the public before the priority date of the patent in suit have been validly established by the testimony of the witness Mr. Amann heard in the

earlier opposition proceedings. The respondent no longer raised any objections in this respect.

The subject of the prior use discloses features A to F of claim 1, as shown in the technical drawings D10 and D11. D10 expressly refers to a "Spherical Burr 4.0" denoted by part number 9774. A burr of this kind is depicted at page 6 of D9, denoted as "Round Burr", with the same part number being listed. Accordingly, feature G is also anticipated. The technical drawings of D11 are considered to be true to scale (with the exception of the longitudinal dimension), particularly with respect to the size of the aperture, according to the testimony of witness Mr. Amann heard in the opposition proceedings (see page 6, 2nd paragraph and page 7, 2nd paragraph, of the testimony). D11 thus makes it possible to measure the dimensions of the aperture, which has a width of about 7 mm, and of the shaft, which has a diameter of about 8 mm. The dimensions are thus within the range defined in option A of feature K, but do not correspond to the relationship according to option B (the aperture width being approximately one-half of the shaft diameter).

The subject of the prior use further fails to disclose features H, I and J. The solid pin of the burr shown in D10 and D11, corresponding to the shank defined in feature F of claim 1, does not comprise a walled chamber with an aperture. The aperture is rather located in the wall of the inner tube. The conical part of the inner tube shown in D10 and D11 cannot be regarded as a shank within the meaning of feature F. Feature F requires that the shank is **mounted to** the **distal end** of the inner tube. In D11 the conical portion forms an integral part of the inner tube and the distal end of the inner tube is

formed by an additional cylindrical portion located distally of the conical portion. This construction is quite different from the claimed features.

5.3 From the above it follows that the subject-matter of claim 1 as granted is new within the meaning of Article 54(1) and (2) EPC vis-à-vis D2 and vis-à-vis the subject of the prior use (D9 to D13).

6. Inventive step

6.1 D2 represents the closest prior art. As indicated above (point 5.1), claim 1 is distinguished from D2 by features F (and consequently also H to J) and K.

6.2 The objective problem to be solved by feature K is to enhance the efficiency at which large tissue fragments severed by the burr are aspirated through the inner tube. Such large tissue fragments may particularly result from cutting soft tissue and may lead to clogging of the aperture. A large aperture according to feature K avoids this problem and thus renders the device suitable for cutting and aspirating both hard bone tissue and softer tissue such as cartilage. This technical effect is derivable from paragraphs [0004], [0008], [0028] and [0046] of the patent specification.

6.3 As a further advantage, feature F makes it possible to optimize the material properties of the various components of the device. As explained in paragraph [0023] of the specification, a surgical tool with a shank which is separate from the inner tube can be made, for instance, from specially hardened stainless steel, while the inner tube may be fabricated from relatively

soft phosphor bronze, having excellent bearing characteristics (see paragraph [0047]).

6.4 D2 gives no hint towards using different materials for the inner tube 14 and the cutting burr 12. With respect to large tissue fragments, D2 teaches the use of a specific design for the cutting burr, comprising a chip breaker groove ("Spanbrechernut 42") for avoiding large fragments by cutting them into smaller pieces (see page 2, second paragraph). The small tissue fragments can then be aspirated more easily through the three apertures 16 in order to achieve a high tissue-removal rate (page 1, third paragraph, and page 7, second paragraph). The possibility of large tissue fragments remaining after cutting, and the resulting risk of clogging of the apertures, are not addressed in D2, which uses a different procedure. Accordingly, there would be no motivation for the skilled person to modify the three apertures to define the specific large aperture according to feature K of claim 1.

6.5 As explained above (point 5.2), the subject of the prior use (D9 to D13) is confined to showing a tool with its proximal shank mounted to an inner tube, without, however, giving any explanations or indicating any specific advantages. It further shows a large aperture having a width falling within the range defined by option A of feature K, but is also silent with respect to any technical effect thereof. The testimony of the witness Mr. Amann also does not reveal anything with respect to the technical effects provided by features F and K. Moreover, as can be seen from D10 and D11, the aperture is located in the wall of the inner tube and not in the shank, i.e. features H, I and J are neither

disclosed nor suggested by either the prior use or D2. Consequently, a combination of D2 with the subject of the prior use would be based on hindsight, and anyhow would not make it possible to arrive at the subject-matter of claim 1.

6.6 Document D3 (Figures 4 and 5) discloses an inner tube 75 with a tissue working head 71 having a cutting edge 42, which may be equated to the burr defined in feature G of claim 1. As can be seen from Fig. 5, these components are integrally formed by one single part, in contrast to feature F, and there is no hint in D3 to deviate from this concept. The tissue working head further comprises an aperture (mouth 80) of "relatively large area" (see column 8, line 53). This statement is not sufficient, however, to anticipate the specific dimensional relations according to feature K. These can also not be derived by measurement from the (purely schematic) drawings of D3, as already explained above with respect to D2 (see point 5.1). Moreover, the aperture 80 and the chamber 73 are located in the part corresponding to the burr, and not in the wall of the shank as required by features H to J. As described in the paragraph bridging columns 8 and 9, the device of D3 works quite differently from that disclosed in D2, and the problem of clogging of the aperture does not play any role and is not even addressed. Consequently, this combination of documents would also be based on hindsight, and would not make it possible to arrive at the subject-matter of claim 1 either.

6.7 Document D8 is similar to D3 in that the inner tube 4 and the burr are integral (Figures 6 and 7), contrary to feature F, and that the apertures 21 (the width of which

is not specified) are provided in the burr itself, the working principle also being similar to that of D3 and different from that of D2. The same applies to document D6 (cited in the International Search Report) where the inner tube 52 and the burr 44 are also integral with the apertures 50 located in the burr itself. For reasons analogous to those indicated above with respect to D3, the combination of D2 with D8 or D6 does not render obvious the subject-matter of claim 1.

6.8 From the above it follows that the subject-matter of claim 1 of the main request is not obvious, starting from document D2 in combination with the prior use (D9 to D13), or in combination with D3, D6 or D8. The subject-matter of claim 1 as granted therefore involves an inventive step within the meaning of Article 56 EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

D. Sauter M. Noël