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**Datasheet for the decision
of 10 December 2014**

Case Number: T 0989/11 - 3.2.02
Application Number: 02765997.8
Publication Number: 1435854
IPC: A61B17/32
Language of the proceedings: EN

Title of invention:

FLEXIBLE INNER TUBULAR MEMBER AND ROTARY TISSUE CUTTING
INSTRUMENT HAVING FLEXIBLE INNER TUBULAR MEMBER

Applicant:

Medtronic Xomed, Inc.

Headword:

Relevant legal provisions:

EPC Art. 56, 123(2)

Keyword:

Inventive step - main and first auxiliary requests (no)
Amendments -
extension beyond the content of the application as filed -
second auxiliary request (yes)

Decisions cited:

Catchword:



**Beschwerdekammern
Boards of Appeal
Chambres de recours**

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Case Number: T 0989/11 - 3.2.02

**D E C I S I O N
of Technical Board of Appeal 3.2.02
of 10 December 2014**

Appellant: Medtronic Xomed, Inc.
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Decision under appeal: **Decision of the Examining Division of the
European Patent Office posted on 3 December 2010
refusing European patent application
No. 02765997.8 pursuant to Article 97(2) EPC.**

Composition of the Board:

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

Summary of Facts and Submissions

- I. The applicant has appealed the Examining Division's decision, dispatched on 3 December 2010, to refuse European patent application No. 02 765 997.8.
- II. The impugned decision was based on the ground that the subject-matter of claim 1 of the main and the auxiliary requests then on file did not involve an inventive step over the combination of documents:
- D1: WO-A-01/56481;
D3: EP-A-0 986 989.
- III. The notice of appeal was received on 2 February 2011 and the appeal fee was paid on the same day. The statement setting out the grounds of appeal was received on 12 April 2011.
- IV. The Board summoned the appellant to oral proceedings and set out its preliminary opinion in a communication dated 19 September 2014.
- V. The oral proceedings took place on 10 December 2014.
- VI. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the main request or, in the alternative, of one of the first and second auxiliary requests, all filed with letter dated 10 November 2014.
- VII. The following document is also mentioned in the present decision:
- D2: WO-A-97/03611.

VIII. Claim 1 of the main request reads as follows:

"A flexible inner tubular member for being rotated in a longitudinally bent outer tubular member of a rotary tissue cutting instrument to cut anatomical tissue, said flexible inner tubular member comprising an elongate inner tube (34) having a central longitudinal axis, a rotatably drivable proximal end, a distal end having a cutting member (36) to cut anatomical tissue, a cylindrical wall defining a lumen in said inner tube, and a helical cut (39) in said inner tube extending lengthwise along said cylindrical wall in a helical path about said central longitudinal axis and extending radially through said cylindrical wall, said helical cut extending around said central longitudinal axis in a first direction; and a spiral wrap (68) disposed over said helical cut including a strip of material wound over said inner tube in a second direction, opposite said first direction, and having ends secured to said inner tube, said helical cut and said spiral wrap defining a flexible region in said inner tubular member allowing said inner tubular member to be rotated within the outer tubular member while conforming to the shape of the outer tubular member; characterized in that said helical cut defines a plurality of serially arranged, helical tube segments (42), with adjacent ones of said tube segments being integrally, unitarily connected to each other, and wherein said helical cut is formed in a dovetail pattern with adjacent ones of said segments interlocked by a plurality of tenons (48) in interlocking engagement with a corresponding plurality of mortises (50); wherein said mortises have straight base edges (58) and said tenons have straight edges (60) complementary to said base edges; and further wherein said helical cut defines a helix angle of 70°

with said central longitudinal axis, said straight base edges (58) are disposed in a plane at an angle with said central longitudinal axis equal to said helix angle, said straight edges (60) are disposed in a plane at an angle with said central longitudinal axis equal to said helix angle and said spiral wrap is oriented on said inner tube at an angle supplementary to said helix angle."

Claim 1 of the first auxiliary request corresponds to claim 1 of the main request except for the addition of the following sentence at the end of the claim:

"and wherein said angle of said spiral wrap is 110°."

Claim 1 of the second auxiliary request corresponds to claim 1 of the main request except for the addition of the following sentence at the end of the claim:

"and wherein said helical cut defines a helically cut region in said inner tube, said helically cut region having a distal end portion, a proximal end portion and a central portion between said distal and proximal end portions, said helical cut having a uniform first pitch along said central portion and a uniform second pitch, greater than said first pitch, along said distal and proximal end portions."

- IX. Claim 1 of the main request and the first auxiliary request respectively differ from claim 1 of the main request and the first auxiliary request on which the impugned decision was based only in the definition of the helix angle and the angle of the spiral wrap, which, in the latter requests, were respectively claimed as being "substantially 70°" and "substantially

110°".

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

a) *Main request*

One of the problems addressed by the invention was to provide an improved flexible inner tubular member of a rotary tissue cutting instrument in surgery, with greater flexibility, durability and reliability than those of the prior art. The invention also aimed at facilitating bending of the instrument proximate to a cutting tip. It also sought to provide an inner tubular member which could be safely rotated at higher speeds, in order "to transmit torque and to effect increased aspiration". All this was achieved by an inner tubular member with a helical cut in a dovetail pattern resulting in interlocked, helical tube segments extending in series from a proximal portion to near the cutting tip of the tissue cutting instrument, in combination with at least one spiral wrap over the tube segments. Moreover, the specific helix angle of 70° of the helical cut was associated with superior properties as it allowed to have a much thinner wall of the inner tubular member, which resulted in a larger internal diameter. This further contributed to better torque transmission and aspiration capabilities.

Document D1 could be considered as a suitable starting point for the skilled person faced with the problems addressed by the invention.

However, document D1 was concerned with providing

multiple spiral wraps and did not mention any other type of support on an inner member. In particular, document D1 did not comprise a mortise/tenon shaft with an interlocking dovetail configuration according to claim 1 on the inside of an outer spiral wrap. The shaft that it comprised was located as the outermost member with respect to a stationary tube, not as the innermost member. Replacing only one spiral wrap as the inner member with a completely different structure was purely based on hindsight, particularly as it increased the cost of the instrument. There was also nothing that hinted or suggested that anything other than the helical or spiral cut already provided in the inner tube would be necessary to provide greater flexibility.

Document D3 described a shaft with a helical slit or cut forming teeth and recesses, but did neither teach nor suggest that a spiral wrap should be provided around the shaft. Moreover, document D3 described the slit in the inner tube as winding in a helical path and as meandering back and forth about it (figure 2). This defined alternating teeth and recesses with respective straight edges. However, there was neither a teaching that these straight edges were disposed in respective common planes nor that they were disposed in planes oriented at an angle with the central longitudinal axis equal to the helix angle of the helical path. Also, the helix angle of the helical path was not disclosed as being 70°. Rather, document D3 taught a "helix as shallow as possible" as derivable from its drawings. Furthermore there was no teaching in D3 that its design could be applied to "small-diameter tubes" of the kind disclosed in

document D1, in particular on page 8, first full paragraph. The skilled person, when wanting to combine documents D1 and D3 would, if anything, position the shaft of document D3 as the outermost rotating shaft with internal spiral shafts as taught by document D1. Hence, even adapting the helical path of document D3 to fit the helix angle in document D1 would not result in the claimed invention.

Document D2 did not disclose more than document D3. In particular, it also suggested a "helix as shallow as possible" to increase flexibility, as derivable from page 16, first paragraph, the paragraph bridging pages 16 and 17 and the paragraph bridging pages 18 and 19. Such a "shallow helix" was therefore a "common thinking" in the prior art.

The helical cuts of documents D2 and D3 were aimed at avoiding separation of adjacent tube segments. More specifically, document D3 was concerned with the adaptation of the inner tube for oscillation, defined as "continuous change of the rotational direction of the inner tube relative to the outer tube". This was different in principle from the problems addressed by the claimed invention.

The problem of improving the torque transmission properties of document D1 was already solved by the provision of multiple spiral wraps. None of the cited documents recognised that the problems of the invention could be solved through the combination of the specifically configured helical cut and the spiral wrap disposed over it as recited in claim 1. It followed that the teaching

of the cited documents, considered singly or in any reasonable combination, would not render obvious the subject-matter of claim 1.

b) *First auxiliary request*

In addition to the arguments presented in support of the main request, neither document D1 nor document D3 motivated the skilled person to provide a spiral wrap with an angle (of 110°) supplementary to the helix angle, as claimed in claim 1 of the first auxiliary request. This angle further contributed to obtaining greater flexibility and reliability of the surgical instrument.

It followed that the subject-matter of claim 1 of the first auxiliary request was inventive over the prior art.

c) *Second auxiliary request*

Compared to claim 1 of the main request, the added features of claim 1 of the second auxiliary request were derived from claim 13 of the application as originally filed.

The fact that the helical cut defined a helix angle of 70° with the central longitudinal axis of the inner tube was not in contradiction with the helical cut also defining three different portions with different pitches. Claim 1 did not require the defined helix angle to be uniform along the whole helical cut. Rather, this angle might only be present in a single winding of the helical cut. Such a configuration was encompassed by the claims

as originally filed. It was also contemplated in the description as originally filed, since from page 24, lines 8 to 9 and the paragraph bridging pages 25 and 26 several possible configurations with different helix angles were disclosed.

It followed that the subject-matter of claim 1 of the second auxiliary request had a basis in the application as originally filed, thereby complying with Article 123(2) EPC.

Reasons for the Decision

1. The appeal is admissible.
2. The invention concerns elongated, flexible, catheter-like surgical tools for cutting tissue. Such surgical tools typically comprise a rotating cutting head for abrading tissue within a body, an irrigation conduit and a vacuum line for aspirating debris and the irrigation fluid. They are normally used for knee surgery or, as the present application suggests, for surgery of the head and the neck.

The invention aims at ensuring a high degree of flexibility of the tool, so as to achieve an easy positioning of the cutting head, while still enabling the transmission of high torque to the cutting head and an effective aspiration, in order to prevent clogging.

3. Main request
 - 3.1 All cited documents relate to a surgical tool with a rotating tubular member having a cutting head. However, the Board considers document D1 as the closest prior

art, since it is the only one which discloses an inner tube with a helical cut and a spiral wrap wound around it, both disposed within an outer tube. Such a layered structure, which is also defined in claim 1 of the main request, is not disclosed in either of documents D2 and D3.

3.2 Document D1 discloses a flexible inner tubular member (14 in figures 1 and 2) for being rotated in a longitudinally bent outer tubular member (18 in figure 1) of a rotary tissue cutting instrument (10 in figure 1) to cut anatomical tissue (page 1, first paragraph), said flexible inner tubular member comprising:

an elongate inner tube (34 in figures 1 and 2) having a central longitudinal axis, a rotatably drivable proximal end (32 in figure 1), a distal end having a cutting member (36 in figures 1 and 2) to cut anatomical tissue, a cylindrical wall defining a lumen in said inner tube (page 8, second full paragraph, second sentence), and a helical cut (40 in figure 2) in said inner tube extending lengthwise along said cylindrical wall in a helical path about said central longitudinal axis and extending radially through said cylindrical wall (page 9, first paragraph, first sentence), said helical cut extending around said central longitudinal axis in a first direction (page 9, first paragraph, second sentence); and

a spiral wrap (42 in figure 2) disposed over said helical cut including a strip of material wound over said inner tube in a second direction, opposite said first direction (page 9, second paragraph, first to third sentences), and having ends secured to said inner tube (sentence bridging pages 9 and 10), said helical

cut and said spiral wrap defining a flexible region (39 in figure 1) in said inner tubular member allowing said inner tubular member to be rotated within the outer tubular member while conforming to the shape of the outer tubular member (sentence bridging pages 9 and 10);

wherein said helical cut defines a plurality of serially arranged, helical tube segments (each defined by a full turn of helical cut 40), with adjacent ones of said tube segments being integrally, unitarily connected to each other; and wherein said helical cut defines a helix angle of 70° with said central longitudinal axis (page 10, first full paragraph, last but one sentence), and said spiral wrap is oriented on said inner tube at an angle supplementary to said helix angle (page 9, second paragraph, seventh sentence).

3.3 The subject-matter of claim 1 differs from the disclosure of document D1 in that the helical cut is formed in a dovetail pattern with adjacent ones of the helical tube segments interlocked by a plurality of tenons in interlocking engagement with a corresponding plurality of mortises; wherein said mortises have straight base edges and said tenons have straight edges complementary to said base edges and said straight base edges are disposed in a plane at an angle with said central longitudinal axis equal to the helix angle of the helical cut, said straight edges being disposed in a plane at an angle with said central longitudinal axis equal to said helix angle.

3.4 As the appellant also submitted, these differentiating features have the effect of maintaining a high degree of flexibility while increasing the torque transmission capability along the inner tube in both directions of

rotation, due to the interlocking of the mortises and tenons along the circumference of said inner tube.

The technical problem to be solved may therefore be regarded as enabling a more efficient cutting action in areas which are difficult to reach.

3.5 The Board notes that the definition of the differentiating features in claim 1 amounts to a requirement that the helical cut should be formed in a dovetail pattern with the single dovetail elements being shorter than half the circumference of the tube.

Evidently, such a pattern necessarily comprises a plurality of mortises and tenons in helical tube segments as claimed. The fact that the mortises and tenons have straight (base) edges oriented at the same angle as the helical cut is also inherent in the definition of a dovetail pattern.

Document D3 shows a rotary tissue cutting instrument (1 in figure 1 and paragraph [0010]) with an inner tube (3 in figure 1) intended to be rotated within a longitudinally bent outer tubular member (2 in figure 1). The inner tube has a helical cut in a dovetail pattern comprising more elements along the circumference of the tube (5 in figure 2). Hence, document D3 discloses all the differentiating features as identified above.

As the appellant argued, in document D3 these features are generally intended to permit effective operation in an oscillating manner (paragraph [0009]), i.e. when the direction of rotation of the inner tube is frequently changed, in order to improve the cutting action (paragraph [0008], third sentence). More particularly,

however, they are proposed in order to provide sufficient torque transmission in both directions when the inner tube is operating in the oscillating manner (paragraph [0009], last but one sentence). Hence, they addressed the same technical problem as defined above.

It follows that the skilled person would apply the teaching of document D3 to the inner tube of document D1, thereby arriving at subject-matter of claim 1 without exercising any inventive activity.

- 3.6 The appellant argued that the skilled person would not foresee a dovetail pattern for helical cut 40 of document D1, but rather for the outermost spiral wrap, if anything. The Board does not share this view, since the torque to be transmitted to the cutting tool of document D1 is directly applied to the element provided with helical cut 40 in document D1, i.e. the innermost element of inner tube 34. This is made clear from the structure of inner tube 34, with the element provided with helical cut 40 extending to rotatably drivable proximal end 32, and with the outer strips being wrapped around only a spirally cut region of the tube (page 9, second paragraph, first two sentences).

The appellant's argument that the straight edges of the dovetail pattern as taught in document D3 would not be disposed at an angle with the central longitudinal axis equal to the helix angle of the helical cut is also not convincing. Realistically, for mere ease of manufacture, a dovetail pattern provided along a predetermined direction, as disclosed in figure 2 of document D3, will result in the straight base edges of said pattern presenting the same angle with respect to the central longitudinal axis of the inner tube, unless there are special reasons for not doing so. Document D3

does not mention any such reason. From figure 2 it cannot be established either that there should be a relative inclination between the general direction of the helical cut (dash-dot line 53) and the direction along which the straight base edges lay (dashed lines).

The fact that the helix angle of the helical cut of document D3 is not disclosed as being 70° is not decisive either. Such an angle of the helical cut is already disclosed in document D1. Moreover, contrary to the appellant's assertion, the angle of the dovetail pattern of document D3 is disclosed as being in a range which includes 70° (derivable from the pitch of the helical cut and the diameter of the tube as disclosed in paragraph [0021] and paragraph [0027], last but two sentence). Therefore, the appellant's argument based on the disclosure of document D2 that a "shallow helix angle" different from 70° was "common thinking" in the prior art cannot be followed. As a result, when applying the teaching of document D3 to the inner tube of document D1, the skilled person would have no reason to change the helix angle of 70° of the helical cut of document D1.

As regards the argument that the design of document D3 could not be applied to "small-diameter tubes" of the kind disclosed in document D1, the Board notes that both documents D1 and D3 are concerned with tubular members of the same diameter (D1, page 8, first full paragraph, first sentence; D3, column 7, lines 42 to 43).

- 3.7 For these reasons, the subject-matter of claim 1 of the main request is not patentable under Article 52(1) EPC, since it does not involve an inventive step

(Article 56 EPC).

4. First auxiliary request

Claim 1 of the auxiliary request does not differ in substance from claim 1 of the main request. The only difference in wording is the explicit definition that the angle of the spiral wrap is 110° . However, such a definition is already implicitly present in claim 1 of the main request, since there the angle of the spiral wrap is defined as "supplementary" to the helix angle of 70° .

It follows that the subject-matter of claim 1 of the first auxiliary request is not inventive either, for the same reasons as explained above.

5. Second auxiliary request

Claim 1 of the second auxiliary request prescribes a helix angle of the helical cut of 70° with the central longitudinal axis of the inner tube and, at the same time, that the helical cut defines a helically cut region with three different portions having different pitches.

For a tube with a uniform diameter, a helical cut with a certain helix angle as defined in the present application corresponds to a certain pitch of the helical cut along the tube. It follows that different pitches of the portions of the helically cut region as claimed must also result in different helix angles in these portions.

The appellant argued that claim 1 had to be interpreted as requiring that the defined helix angle was not

uniform along the whole helical cut. Its value of 70° could be in relation with a single winding of the helical cut, which would then have a freely variable pitch.

In the Board's view, expressed during the oral proceedings, in the application as filed whenever a specific helix angle is defined for an embodiment, that embodiment does not feature a freely variable pitch of the helical cut. Hence, the interpretation of claim 1 proposed by the appellant was not originally disclosed in the application as filed.

The preferred embodiment described in the paragraph bridging pages 23 and 24, which comprises a helical cut with a helix angle of 70° , does not relate to a configuration with a freely variable pitch. The passages on pages 24 to 26 referred to by the appellant, which envisage different helix angles, do not mention any specific value of the latter. Even when the application as filed mentions a helix angle α in relation with a helically cut region having portions of different pitches (for example page 11, first paragraph), it does so with reference to a whole portion and does not specify the value of the helix angle. Finally, claim 13 of the application as originally filed does not depend on any of claims 1 to 5 as originally filed, from which the remaining features of claim 1 of the second auxiliary request are derived.

Whether the claims as originally filed encompassed the appellant's interpretation as explained above is not decisive as long as the latter is not directly and unambiguously disclosed in the application as filed.

For these reasons, the Board concludes that the subject-matter of claim 1 of the second auxiliary request extends beyond the content of the application as filed, in breach of Article 123(2) EPC.

6. At least for these reasons, none of the appellant's requests can be allowed.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



D. Hampe

E. Dufrasne

Decision electronically authenticated