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**Datasheet for the decision  
of 19 January 2010**

**Case Number:** T 0405/07 - 3.2.02

**Application Number:** 01203180.3

**Publication Number:** 1151722

**IPC:** A61B 17/04

**Language of the proceedings:** EN

**Title of invention:**

Surgical tape for treating female urinary incontinence

**Patentee:**

ETHICON, INC.

**Opponents:**

- (1) Boston Scientific Corporation
- (2) SOFRADIM PRODUCTION
- (3) Edward Tomlinson
- (4) Aesculap AG

**Headword:**

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**Relevant legal provisions:**

EPC Art. 123(2)

**Relevant legal provisions (EPC 1973):**

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**Keyword:**

"Extended subject-matter (yes)"

**Decisions cited:**

T 0676/90, T 0331/87, T 0962/98, T 0025/03

**Catchword:**

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Case Number: T 0405/07 - 3.2.02

**D E C I S I O N**  
of the Technical Board of Appeal 3.2.02  
of 19 January 2010

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**Decision under appeal:** Interlocutory decision of the Opposition  
Division of the European Patent Office posted  
16 January 2007 concerning maintenance of  
European patent No. 1151722 in amended form.

**Composition of the Board:**

**Chairman:** M. Noël  
**Members:** D. Valle  
M. J. Vogel

## Summary of Facts and Submissions

I. The present decision concerns the appeals of:

- the patentee (appellant I),
- the opponent I (appellant II), and of
- the opponent IV (appellant III)

against the decision dated 16 January 2007 of the Opposition Division to maintain the European patent No. 1 151 722 in amended form.

The opponents II and III are respectively respondents I and II in the present appeal procedure.

II. Appellant I lodged an appeal on 19 March 2007 and paid the appeal fee on the same day. Its statement setting out the grounds for appeal was received on 22 May 2007, along with amended sets of claims.

Appellant II lodged an appeal on 9 March 2007 and paid the appeal fee on the same day. Its statement setting out the grounds for appeal was received on 23 April 2007.

Appellant III lodged an appeal on 8 March 2007 and paid the appeal fee on the same day. Its statement setting out the grounds for appeal was received on 14 May 2007.

III. Upon request of all the appellants and of the respondent II oral proceedings took place on 19 January 2010.

The appellant I requested that the decision under appeal be set aside and that the patent be maintained as granted (main request) or as an auxiliary measure on the basis of the first auxiliary request filed with its statement of grounds or on the basis of the second, third or fourth auxiliary requests filed with its letter of 17 December 2009 or on the basis of the fifth auxiliary request filed with its statement of grounds.

The appellants II and III requested that the decision under appeal be set aside and that the patent be revoked.

The respondents I and II requested that the appeal of the appellant I be dismissed.

IV. Claim 1 of the various requests reads as follows:

Main Request:

"A tape for treating female urinary incontinence characterized in that the tape comprises a netting (26) enclosed by a thin plastics sheath (34)."

First auxiliary request:

"A tape for treating female urinary incontinence by attaching a first curved needle-like element (21A) at one end of the first element to a first end of the tape (26) and a second curved needle-like element (21B) at one end of the second element to a second end of the tape (26), the elements being constructed to be connectable independently of each other with the second end of a shank having a handle at a first end of the

shank and a second end adapted to receive the first curved needle-like element (21A) or the second curved needle-like element (21B), and passing the elements into the body via the anterior (suburethral) vaginal wall, the elements being dimensioned to extend from the inside surface of the vagina wall over the back of the pubic bone to the outside of the abdominal wall, characterized in that the tape comprises a netting (26) enclosed by a thin plastics sheath (34)."

Second auxiliary request:

"A tape for treating female urinary incontinence characterized in that the tape comprises a netting (26) enclosed by a thin plastics sheath (34), wherein the sheath is removable when the tape has been positioned in the correct position as a sling around the urethra."

Third auxiliary request:

"A tape for treating female urinary incontinence characterized in that the tape comprises a netting (26) enclosed by a thin plastics sheath (34), wherein a visible marking (38) is provided on the sheath (34) at the longitudinal centre thereof."

Fourth auxiliary request:

"A tape for treating female urinary incontinence characterized in that the tape comprises a netting (26) enclosed by a thin plastics sheath (34), wherein the sheath (34) is perforated at the longitudinal centre thereof."

Fifth auxiliary request:

"A tape for treating female urinary incontinence characterized in that the tape comprises a netting (26) enclosed by a thin plastics sheath (34), a first curved needle-like element (21A) attached at one end of the first element to a first end of the tape (26) and a second curved needle-like element (21B) attached at one end of the second element to a second end of the tape (26), the elements being constructed to be connectable independently of each other with the second end of a shank having a handle at a first end of the shank and a second end adapted to receive the first curved needle-like element (21A) or the second curved needle-like element (21B), and the elements being intended to be passed into the body via the anterior (suburethral) vaginal wall and being dimensioned to extend from the inside surface of the vagina wall over the back of the pubic bone to the outside of the abdominal wall."

V. In their written submissions and at the oral proceedings the appellants II and III argued that none of the requests complied with Article 123(2) EPC.

Also the respondents I and II argued that at least the main and the auxiliary requests 1 to 4 did not comply with Article 123(2) EPC.

In summary, they took the view that the subject-matter of claim 1 as granted (main request) extended beyond the content of the application as filed, principally because the claimed invention was changed from a surgical instrument to a tape which was only a part of the instrument, and because an unacceptable

generalisation occurred through the omission from the claim as originally filed of a number of essential features related to the instrument.

VI. In its written submission and at the oral proceedings the appellant I contested the objections of the appellants II and III and of the respondents and argued substantially as follows.

The main claims of all requests complied with Article 123(2) EPC. The application as originally filed described a tape in isolation, not only in combination with the needles or other components of the surgical instrument.

In particular, Figure 3 showed a tape not connected with the needle. At page 3, line 24 to 26 of the application as filed, it was mentioned, with reference to Figure 6 of document PCT/SE95/00964 (WO 96/06567) incorporated by reference, that the tape should be connected to the needles, and on page 1, line 30 of the same application in relation to Figure 3, that the tape was to be connected with the needle, which clearly indicated that the connection had not yet taken place. At most, Figure 6 of the application could support the disclosure of an invention comprising a tape connected with two needles but not that of a surgical instrument comprising additionally, a shank having a handle. In any case, however, the indispensability of the needles was based on a misconception of the invention which, clearly, could be considered to centre around the tape.

Claim 1 of the original disclosure should not be used as the only basis for supporting the amended versions



of the claims. The original main claim could be replaced by a claim having a broader scope if there was sufficient support for it in the whole content of the original application. The sole issue to be decided by the Board in this case was whether the original application as a whole disclosed a tape in isolation. It was therefore irrelevant whether a tape as such was originally claimed or not.

All the main claims of the various requests passed the three-point test provided in decision T 331/87. This test was misapplied by the Opposition Division, as far as the main request was concerned. While the invention generally aimed at improving the surgical instrument known from WO 96/06567 as mentioned above, (see page 1, lines 9 to 22 of the present application), the relevant technical problem to be solved by the application was related to the tape only since it represented the only contribution to the invention, as was made clear by the charactering features of claim 1 as granted. Needles and shank were not essential to the present invention and therefore were not essential for its definition. In determining whether a feature was essential, the proper question to be posed was whether this feature was responsible for the technical effect to be obtained by the invention and not whether some additional features were necessary to create a more complex device incorporating this feature (the instrument as a whole).

It was not unusual in the practice of the EPA to grant a claim restricted to a component of a device, even if such component could be practically used only in combination with further elements of the device, and even if it was initially described only in relation

with these further elements. In this manner, the applicant was assured that he could practically exploit that component of the invention which could be produced and marketed independently of the other elements (see Guidelines, C.III.4.8a). In the present case, even if the tape could be regarded as having a practical utility only in combination with the needles and shank, this did not prevent a claim to the tape itself.

### **Reasons for the Decision**

1. The appeal is admissible.
2. *Article 123(2) EPC*
  - 2.1 Main request

Claim 1 of the main request does not comply with Article 123(2) EPC because there is no adequate support in the original application for an invention consisting merely of a tape.

Consistently, throughout the original disclosure, it is clearly stated that the invention relates to a surgical instrument for treating female urinary incontinence, of the type described in PCT/SE95/00964 (WO 96/06567) which is incorporated by reference, comprising in particular a shank having a handle and two curved needle-like elements each attached at one end thereof to one end of a tape (see title; page 1, lines 6 to 11; page 2, lines 6 to 33; claim 1 and figures of the originally filed application). Therefore, the application as originally filed never presents the

invention as being a tape taken in isolation but always in combination with the other elements of a surgical instrument.

In the drawings, Figures 1 and 2 are respectively a side and a plan view of the surgical instrument as a whole, according to the invention, whereas Figures 3 to 6 are, typically, additional views showing details of the invention. Certainly, Figure 3, which is an exploded view of different parts to be connected to each other, shows the tape 26 separated from the needle 21. However a figure can never be considered independently on its own, but has to be interpreted in the general context of the application as a whole (see T 676/90). In other words, the content of an application is defined not only by features or elements mentioned or shown therein, but also by their relationship to each other.

The Opposition Division correctly applied the three-point test referred to in T 331/87 in assessing that the removal of features from the original claim 1 violated Article 123(2) EPC. As demonstrated above, the handle, the shank and at least one needle are essential and clearly indispensable parts of the surgical instrument illustrated as a whole in Figure 1, even if the improvement only consists in enclosing the netting of the tape by a plastics sheath with a view to facilitate insertion and removal of the tape into and from the body tissues.

According to another approach, claiming in isolation an element which was originally disclosed only as part of a whole entity represents an unallowable intermediate

generalisation, which is admissible only if it can be derived from the application as filed that such element is not closely related to the other elements of the combination and can be applied to a more general context (see T 962/98). In the present case, however, the invention is defined by the relationship between the tape, the handle, the shank and the needles, which all together constitute the surgical instrument. A more general context is not present, so that claiming a tape in isolation extends the protection to using the tape for treatments of female urinary incontinence without the need of any handle, shank and needles. This is not what the original application discloses. In order to assess whether an amendment complies with the requirements of Article 123(2) EPC, the question is not whether the amended subject-matter is consistent with the description and/or the drawings but rather whether the amendment is directly and unambiguously derivable therefrom. Stated another way, it is not admissible to extract isolated features from a set of features originally disclosed in combination for defining a new invention (see also case T 25/03).

The Board is aware that broadening the scope of a claim from its original formulation is not precluded by Article 123(2) EPC, provided however that the reformulated subject-matter remains within the frame imposed by the application as filed. This is obviously not the case in the present situation as demonstrated above.

Also the example given by the appellant I with reference to the Guidelines for Examination C.III.4.8a (revised version of June 2005) is not appropriate and

failed to convince the Board since the quoted paragraph of the Guidelines is concerned with clarity and not with extension of the claimed subject-matter. More specifically, the quoted paragraph deals with a case where a claim defines a first entity (cylinder head) in relation with the second entity (engine) which is not part of the claimed entity, such that the application is normally entitled to independent protection for the first entity per se.

In the present case the tape is clearly a part of the surgical instrument which was originally claimed and constantly presented in the application as being the invention, so that the applicant is only entitled to the combination forming the surgical instrument.

Accordingly claim 1 of the main request does not comply with the requirements of Article 123(2) EPC.

## 2.2 Auxiliary requests

Since the first to fifth auxiliary requests comprise each a claim 1 which is directed to a tape, the same reasoning and conclusion as for the main request apply to the claims of the various auxiliary requests, despite the incorporation of one or more additional elements of the surgical instruments. As a matter of fact, each of these requests defines principally a tape having a specific combination of features which is not supported as such by the application as filed and, therefore, extends its subject-matter contrary to Article 123(2) EPC.

In particular, the Board could not find in the contested decision any convincing justification for the maintenance of the fourth auxiliary request (fifth auxiliary request in the present appeal). Contrary to the findings of the first instance the Board is satisfied that the addition of some features related to the instrument does not remove the fundamental deficiency, present in all requests, that an invention is now presented as a tape for treating female urinary incontinence, which was neither contemplated nor supported by the application as originally filed.

As a consequence, the claims according to the first to fifth auxiliary requests also do not comply with the requirements of Article 123(2) EPC.

## **Order**

### **For these reasons it is decided that:**

1. The decision under appeal is set aside.
2. The patent is revoked.

The Registrar:

The Chairman:

D. Sauter

M. Noël