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**D E C I S I O N**  
**of 26 November 2003**

**Case Number:** T 0548/01 - 3.2.2

**Application Number:** 96306567.7

**Publication Number:** 0763345

**IPC:** A61B 10/00

**Language of the proceedings:** EN

**Title of invention:**

Uterine endometrial tissue sample brush

**Patentee:**

VANCE PRODUCTS INCORPORATED d/b/a COOK UROLOGICAL INCORPORATED

**Opponent:**

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**Headword:**

-

**Relevant legal provisions:**

EPC Art. 84, 123(2), 56

**Keyword:**

"Clarity and adequate support (yes, after amendments)"  
"Inventive step (yes)"

**Decisions cited:**

-

**Catchword:**

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Case Number: T 0548/01 - 3.2.2

**D E C I S I O N**  
**of the Technical Board of Appeal**  
**of 26 November 2003**

**Appellant:**

VANCE PRODUCTS INCORPORATED d/b/a COOK  
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**Representative:**

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**Decision under appeal:**

**Decision of the Examining Division of the  
European Patent Office posted 24 November 2000  
refusing European application No. 96306567.7  
pursuant to Article 97(1) EPC.**

**Composition of the Board:**

**Chairman:** W. D. Weiß  
**Members:** M. G. Noel  
E. J. Dufrasne

## Summary of Facts and Submissions

I. European patent application No. 96 306 567.7 was refused by the Examining Division on the grounds that the claimed subject-matter lacked clarity (Article 84 EPC) and inventive step (Article 56 EPC) vis à vis the prior art documents:

D1: US-A-4 227 537, and

D2: GB-A-2 159 420.

II. The reasons given by the Examining Division were that the specification of the bristle material having a stiffness equivalent to that of nylon -6,12 at a diameter of about 0.076 to 0.152 mm lacked clarity in the absence of any mention of the bristle length and of a clear definition of the conditions of the test. The subject-matter of claim 1 was also lacking inventive step in view of the teaching of documents D1 and D2 which disclosed bristles having outside diameters and a brush length falling within the ranges as claimed. In order to arrive at an acceptable main claim, the first instance suggested, however, to restrict the scope of claim 1 to the specific material and dimensions disclosed in the application as filed.

III. The appellant (applicant) lodged an appeal against this decision and filed a statement of grounds on 4 April 2001.

IV. In response to a communication of the Board dated 18 June 2003, the appellant, by letter dated 20 September 2003, submitted a complete set of amended application documents.

It requested that the decision under appeal be set aside and that a patent be granted on the basis of these pieces of documents, namely:

Claims: 1 to 22

Description: pages 1 to 3; 3a; 4 to 21

Figures: 1 to 8.

V. Claim 1 reads as follows:

"A uterine endometrial tissue sample brush (10) comprising a flexible core (12) having a proximal core end (14) and a distal core end (16); and a brush member (18) carried adjacent the distal core end (16), the brush member having a plurality of axially spaced resilient bristles (20) having a free outside diameter suited to maintain patient comfort yet comprehensively contact the undilated uterine canal (38); whereby the brush member (18) is about 3 to 5 cm long and with the free outside diameter being about 5.08 to 7.62 mm, the bristles (20) are axially spaced about 0.5 to 1.5 mm apart, said plurality of bristles (20) comprising at least a plurality of first bristles (120) made of nylon-6,12 at a diameter of about 0.076 to 0.152 mm, or of a synthetic, plastic or polymeric material having a stiffness equivalent to that of said nylon at said diameters."

## Reasons for the Decision

1. The appeal is admissible.
2. *Amendments*

Claim 1 is based on claims 1, 19 and 21 as originally filed, supplemented by more specific features drawn up from the description as originally filed, in particular page 10, lines 4 to 26 and page 11, lines 1 to 13;

claim 2 is supported by original claim 3, supplemented by features from the original description on page 15, lines 29 to 31;

claim 3 is supported by the original description on page 15, lines 22 to 23;

claim 4 is supported by the original description on page 14, lines 14 to 19;

claim 5 is supported by the original description on page 13, lines 15 to 26;

claims 6 to 22 are supported by original claims 2 to 14; 16; 18 to 20, respectively.

The introductory part of the description was adapted to claim 1 as amended and the passages which referred to the method for sampling uterine endometrial tissue were deleted from the description so as to avoid any

misleading interpretation of the claims and any interference with Article 52(4) EPC.

Therefore, the amendments made to the application as a whole are clear and not such as to extend its subject-matter beyond the content of the application as filed, in accordance with Article 84 and 123(2) EPC. In particular, the invention as now claimed includes the use of nylon - 6,12 with a diameter of about 0.076 to 0.152 mm, and takes these specific material and parameters as a standard for defining a reference stiffness under the normal conditions of use in view of the production of bristles from that material and also from other materials having an equivalent stiffness. A more mathematical or scientific definition of the stiffness is not necessary and would not be supported anyway by the application as originally filed.

3. *Inventive step*

3.1 Document D1 represents the closest prior art. It discloses (see Figures 1, 2A and 2B) a uterine endometrial tissue sample brush 10 comprising a flexible core 22 made of a spirally wrapped pair of wires, and a brush member 14 adjacent the distal core end, the brush having a plurality of axially spaced resilient bristles 14. The bristle section of the brush (Figure 2A) is about 25.4 mm (one inch) long and has an outside diameter (Figure 5) over 6.35 mm (one fourth of an inch). These dimensions may be varied to suit varying requirements (column 4, lines 59 to 60). The bristles may be made of nylon, without further specification (column 4, lines 34 to 35).

With respect to the dimensions as claimed, only the outside diameter of the known brush is comprised within the claimed range of 5.08 to 7.62 mm. The other dimensions are situated outside the ranges as claimed or simply not disclosed, given that no dimensional feature can reasonably be deduced from a schematic representation of the drawings. The mere mention of nylon as a possible material for the bristles is not sufficient to imply a specific stiffness in the absence of any indication of diameter.

- 3.2 The subject-matter of claim 1, therefore, differs from the disclosure of document D1 essentially by the brush member being about 3 to 5 cm long, by the bristles being axially spaced about 0.5 to 1.5 mm apart, and by the use of nylon -6,12 at a diameter of about 0.076 to 0.152 mm or of a synthetic, plastic or polymeric material having an equivalent stiffness for making the bristles. These features provide the tissue sample brush as a whole with good exfoliating and collecting abilities simultaneously, in accordance with the problem as set out in the patent application (cf. paragraph bridging pages 2 and 3).
- 3.3 Document D2 discloses an endocervical sampling brush comprising a spiral wound bristle of 15 to 20 mm in length and of 3 to 7 mm in diameter at its widest end or 5.4 to 7.5 mm according to the dimensional characteristics of the example given on page 2, lines 1 to 8, assuming that the length of the bristles corresponds to the free outside diameter of the brush member. The bristles are formed primarily of a soft nylon (grade quality) having a maximum diameter of 0.06 mm (cf. page 1, lines 55 to 59).

Compared with the dimensions as claimed, only the outside diameter of the brush disclosed in D2 falls within the range of 5.08 to 7.62 mm. The other dimensional features such as the brush length or the axial spacing are outside the claimed ranges or not mentioned at all. As to the stiffness of the bristles, it is supposedly less than the equivalent stiffness as claimed in view of a maximum bristle diameter (0.06 mm) smaller than the inferior limit of the claimed range (0.076 to 0.152 mm).

- 3.4 Thus, even when combining the teachings of documents D1 and D2, the skilled person would not have arrived at a sampling brush having all the specific requirements and properties as those claimed, providing the brush as a whole with an optimal stiffness for the contemplated uterine endometrical application.

Since such a combination of features is not suggested by the prior art documents the subject-matter of claim 1 involves an inventive step within the meaning of Article 56 EPC. The dependent claims can also stand.



## Order

### For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the first instance with the order to grant a patent on the basis of the following documents:

Claims: 1 to 22

Description: pages 1 to 3; 3a; 4 to 21

Figures: 1 to 8.

all submitted by letter dated 20 September 2003.

The Registrar:

The Chairman:

V. Commare

W. D. Weiß