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**Datasheet for the decision  
of 20 February 2015**

**Case Number:** T 0556/11 - 3.2.02

**Application Number:** 00991350.0

**Publication Number:** 1343412

**IPC:** A61B1/32

**Language of the proceedings:** EN

**Title of invention:**  
VAGINAL SPECULUM

**Applicant:**  
Comfortpat B.V.

**Headword:**

**Relevant legal provisions:**

EPC Art. 84, 123(2), 54(2), 111(1)  
EPC R. 43(1), 115  
RPBA Art. 15(3)

**Keyword:**

Clarity - main and auxiliary request I (no)  
Clarity - auxiliary request II (yes)  
Added subject-matter - auxiliary request II (no)  
Novelty - auxiliary request II (yes)

**Decisions cited:**

T 0068/85



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Case Number: T 0556/11 - 3.2.02

**D E C I S I O N**  
**of Technical Board of Appeal 3.2.02**  
**of 20 February 2015**

**Appellant:** Comfortpat B.V.  
(Applicant) Tjalk 17  
6852 DG Huissen (NL)

**Representative:** de Baat, Michiel Anton  
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**Decision under appeal:** **Decision of the Examining Division of the European Patent Office posted on 6 October 2010 refusing European patent application No. 00991350.0 pursuant to Article 97(2) EPC.**

**Composition of the Board:**

**Chairman** E. Dufrasne  
**Members:** M. Stern  
P. L. P. Weber

## **Summary of Facts and Submissions**

I. The applicant lodged an appeal against the decision of the Examining Division, dispatched on 6 October 2010, refusing European application No. 00 991 350.0. The application was refused on the grounds that the different versions of claim 1 then on file did not satisfy the requirements of Articles 84, 123(2) EPC and/or 54(2) EPC concerning clarity, added subject-matter and novelty in view of the following document:

D2: US-A-5 167 222.

II. Notice of appeal was filed on 25 November 2010 and the fee for appeal was paid the same day. A statement setting out the grounds of appeal was received on 16 February 2011.

III. The appellant was summoned on 21 November 2014 to attend oral proceedings on 20 February 2015. In a communication annexed to the summons the Board presented its provisional opinion on clarity (Article 84 EPC).

IV. In an undated letter received by fax on 16 January 2015, the appellant requested postponement of the oral proceedings.

V. By communication dated 20 January 2015, the Board informed the appellant that the oral proceedings would take place as scheduled. In a letter dated 5 February 2015, the appellant announced that it would not be attending the oral proceedings.

VI. The appellant requested in writing 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 auxiliary requests I to XI, all filed with letter dated 17 February 2015. If the Board reached a favourable decision on clarity regarding the main request and auxiliary requests I to III, it was requested to remit the case to the Examining Division for further prosecution under Article 111(1) EPC.

VII. Oral proceedings took place on 20 February 2015 in the absence of the appellant in accordance with Rule 115(2) EPC and Article 15(3) RPBA.

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

"1. Vaginal speculum (1) comprising two spoon blades (3,4) which form a spoon blade assembly and:  
- are intended for introduction into the vagina (25);  
- are elongated in a longitudinal direction; and  
- are located alongside and opposite one another;  
the one spoon blade (4) at one end of the spoon blade assembly being provided with two bodies (6) which together with said one spoon blade form a housing part having a U-shaped cross section and other spoon blade (3) being accommodated between said bodies (6) such that it is hingeable with respect to the one spoon blade (4), wherein an exterior of the housing part having the U-shaped cross section (4,6) is shaped for accommodating said housing part having the U-shaped cross section in the mouth of the vagina (25) after the spoon blades (3,4) have been introduced into the vagina (25); and for holding said housing part having the U-shaped cross section, at least when the spoon blades (3,4) are in a position in which they have been brought together, in place in the mouth of the vagina (25) by the ring (50) of the muscle tissue (30,31) extending around, the mouth of the vagina."

IX. Claim 1 of **auxiliary request I** reads as follows (amendments to claim 1 of the main request are highlighted by the Board):

"1. Vaginal speculum (1) comprising two spoon blades (3,4) which form a spoon blade assembly and:  
- are intended for introduction into the vagina (25);  
- are elongated in a longitudinal direction; and  
- are located alongside and opposite one another;  
the one spoon blade (4) at one end of the spoon blade assembly being provided with two bodies (6) which together with said one spoon blade form a housing part having a U-shaped cross section and other spoon blade (3) being accommodated between said bodies (6) such that it is hingeable with respect to the one spoon blade (4), wherein an exterior of the housing part having the U-shaped cross section (4,6) **is being shaped such that when spoon blades (3,4) have been introduced into the vagina (25)** ~~for accommodating~~ said housing part having the U-shaped cross section **is accommodated** in the mouth of the vagina (25) ~~after the spoon blades (3,4) have been introduced into the vagina (25); and for holding said housing part having the U-shaped cross section, and~~  
**when the spoon blades (3,4) are in the position ready for use, wherein the spoon blades have been introduced into the vagina (25) and** at least when the spoon blades (3,4) are in a position in which they have been brought together,  
**a reactive force acting on the exterior of the housing by the ring (50) of the muscle tissue (30,31) extending around the mouth of the vagina exceeds an expelling force so that said housing part having the U-shaped cross section is held** in place in the mouth of the vagina (25) ~~by the ring (50) of the muscle tissue (30,31) extending around, the mouth of the vagina."~~

X. Claim 1 of **auxiliary request II** reads as follows (amendments to claim 1 of the main request are highlighted by the Board):

"1. Vaginal speculum (1) comprising two spoon blades (3,4) which form a spoon blade assembly and:  
- are intended for introduction into the vagina (25);  
- are elongated in a longitudinal direction; and  
- are located alongside and opposite one another;  
the one spoon blade (4) at one end of the spoon blade assembly being provided with two bodies (6) which together with said one spoon blade form a housing part having a U-shaped cross section and other spoon blade (3) being accommodated between said bodies (6) such that it is hingeable with respect to the one spoon blade (4), wherein an exterior of the housing part having the U-shaped cross section (4,6) is shaped for accommodating said housing part having the U-shaped cross section in the mouth of the vagina (25) after the spoon blades (3,4) have been introduced into the vagina (25); and

**wherein the housing part having the U-shaped cross section is provided with at least one tapering surface (17) that tapers with respect to the longitudinal direction of the speculum in a direction of an external part thereof, on which tapering surface (17) a ring (50) of muscle tissue formed by the musculus sphincter ani externus (30) and/or the musculus bulbocavernosus (31) acts/engages when the speculum (1) is in the position in which it has been inserted in the vagina (25) and is ready for use, such that a compressive force pushing the speculum into the vagina (25) is exerted on said tapering surface (17) for holding said housing part having the U-shaped cross section, at least when the spoon blades (3,4) are in a position in which they have been brought together, in place in the**

mouth of the vagina (25) by the ring (50) of the muscle tissue (30,31) extending around, the mouth of the vagina."

Auxiliary request II also comprises dependent claims 3 to 15 of the main request.

XI. Auxiliary requests III to XI are not relevant for the present decision.

XII. The arguments presented by the appellant which are relevant for the present decision are summarised as follows:

(i) *Postponement of oral proceedings*

Postponement of the oral proceedings scheduled for 20 February 2015 had been requested since the funds for preparing and attending the oral proceedings could not be raised at such short notice. A date in May or June would be acceptable, although fund raising would still be an issue. Due to the Christmas holiday period, the necessary submissions could not be filed until 20 January 2015, a date less than two months from the postal date of the summons.

(ii) *Clarity*

Prior-art vaginal specula comprised means for retaining the speculum in the vagina when the spoon blades were spread. However, the prior-art specula were not suitable to be retained in the vagina when the spoon blades were closed. The present application indicated on page 5, lines 2 to 5 that the speculum could be constructed in a wide variety of ways in order to achieve the retention effect sought according to the

invention. Constrictions, recesses, indentations and tapering surfaces were mere examples of how to construct the shape of the speculum housing. Therefore, limiting the claim to those examples would unduly restrict the scope of the claims. The examples in the application provided instructions which were sufficiently clear for the skilled person to reduce them to practice without undue burden, if necessary with reasonable experiments (T 68/85).

Claim 1 of the main request already contained those specific features of the speculum needed in order to solve the technical problem. These features were provided in the functional definition that the exterior of the U-shaped housing was shaped for holding said part of the U-shaped housing in place in the mouth of the vagina by the ring of the muscle tissue. A skilled person would have no difficulty in designing such a U-shaped housing such that the fleshy ring of muscle tissue could, in some way, grip the housing. It was clear for a skilled person that many options for achieving this effect were possible, as stated in the original application on page 5, lines 2 to 5.

Claim 1 of auxiliary request I recited further features related to the forces acting on the speculum, whereby this claim too met the requirements of Article 84 EPC.

In claim 1 of auxiliary request II, the feature of a tapering surface (17) as disclosed in original claim 2 was added. This feature allowed retention of the U-shaped housing in the mouth of the vagina. Based on the fact that normally an expelling force is present, as disclosed in the application, the skilled person would understand that the tapering direction is the



direction which provides for extra "resistance" to the expelling force. Thus, claim 1 was clear.

(iii) *Novelty*

The vaginal speculum disclosed in D2 was not held in the mouth of the vagina by a ring of muscle tissue when the blades were brought together. In particular, the feature of the tapering surface was absent from the speculum of D2. Although the recesses (16, 17) of D2 comprised a tapering surface, D2 did not disclose positioning these recesses on the U-shaped housing part as claimed. Furthermore, Figure 1 of D2 clearly showed that the U-shaped housing part of D2 was and remained external to the mouth of the vagina.

### **Reasons for the Decision**

1. The appeal is admissible.
2. *Procedural matters*
  - 2.1 Following the summons dated 21 November 2014, the appellant on 16 January 2015 requested postponement of the oral proceedings scheduled for 20 February 2015. It mainly argued that funds for preparing and attending the oral proceedings could not be raised at such short notice, and that submissions could not be filed until 20 January 2015, a date less than two months from the postal date of the summons.
  - 2.2 For the following reasons, the Board did not consider the reasons put forward serious enough to justify the fixing of a new date, in accordance with the notice of the Vice-President of Directorate-General 3 concerning

oral proceedings before the boards of appeal of the EPO, Special edition No. 3, OJ EPO, 2007, H.1, page 181.

Oral proceedings were scheduled to take place about three months after the date of the summons, in accordance with the time limit of at least two months stipulated in Rule 115(1) EPC. It is not contemplated that this time limit should be extended when public holidays, such as Christmas and New Year as in the present case, fall within the time limit. The Board finds it moreover unjustified that the appellant waited almost two months to file its request for another date, instead of filing the request as soon as possible after receiving the summons, at a time when the issues of costs and preparation time must have been already known to the appellant. The Board could also not accept the appellant's most unusual proposition that the oral proceedings requested be delayed until it had raised sufficient funds to bear the costs involved, all the more so since the appellant said it was not sure whether it would have succeeded in raising the necessary funds by May or June.

2.3 The duly summoned appellant did not attend the oral proceedings, as announced in its letter dated 5 February 2015. The proceedings were consequently continued without the appellant, as provided for in Rule 115(2) EPC. In accordance with Article 15(3) RPBA, the appellant was treated as relying only on its written case.

### 3. *Main request*

3.1 The application as originally filed states that the aim of the vaginal speculum according to the invention

resides, in particular, in its specially designed shape which allows the speculum to be held in place in the mouth of the vagina by the muscle tissue around the mouth of the vagina even when the spoon blades are together (page 3, line 29 to page 4, line 2).

- 3.2 Claim 1 defines a vaginal speculum comprising, as structural features, a spoon blade assembly formed by two spoon blades, one of which is provided with two bodies which, together with said one spoon blade, form a housing part having a U-shaped cross section, the other one of the spoon blades being hingeably accommodated between said bodies.

The housing part of the claimed vaginal speculum is further defined by functional features. According to these, an exterior of the housing part having the U-shaped cross section is *shaped for* holding said housing part, at least when the spoon blades are in a position in which they have been brought together, in place in the mouth of the vagina by the ring of the muscle tissue extending around the mouth of the vagina. No structural features for achieving the retention effect are defined.

- 3.3 Article 84 EPC requires that the claims define the matter for which protection is sought in a clear and concise manner and that the claims be supported by the description. Rule 43(1) EPC specifies that the matter for which protection is sought must be defined in terms of the technical features of the invention. These requirements serve the purpose of ensuring that the public is not left in any doubt as to the subject-matter covered by a claim.

Moreover, these requirements imply that a claim must be non-ambiguous and comprehensible for the skilled person, and that a claim must identify all the essential technical features of the invention, these being the features which are necessary in order to obtain a desired effect. The claimed features may be expressed in structural or functional terms, the latter case applying if, from an objective point of view, the features cannot otherwise be defined more precisely without unduly restricting the scope of the claim, and if the functional features provide instructions which are sufficiently clear for the skilled person to reduce them to practice without undue burden (T 68/85, OJ EPO 1987, 228, Reasons 8.4.3). However, an applicant cannot simply define a technical feature as it wishes. Rather, the objectively more precise form must be chosen (T 68/85, Reasons 8.4.2).

- 3.4 As indicated above, in claim 1 the shape of the vaginal speculum is not defined structurally, but only by the effect it may achieve, i.e. of allowing its retention in the mouth of the vagina.

The description discloses some embodiments of a vaginal speculum specifically devised so that the speculum may be retained. In these embodiments, the housing includes, for example, a tapering surface for engagement of the musculus sphincter ani externus and/or the musculus bulbocavernosus (original claim 2; page 10, lines 24 to 28; page 14, lines 1 to 6; Figures 2 and 6 to 8), or a constriction or indentation for engagement of the ring of muscle tissue (original claim 4; page 11, lines 18 to 24; Figures 3 and 4). Although the description also indicates that "the housing can be constructed in a wide variety of ways in order to achieve the retention effect" (page 5, lines 2

to 5), no specific other shapes than those disclosed may be envisioned by the skilled person from the application taken as a whole.

In view of the above, the claimed definition of the shape of the housing just in terms of the retention effect to be achieved is ambiguous. The Board considers therefore that the disclosed structural features for obtaining the desired retention effect are essential for a clear and unambiguous definition of the invention. In fact, original claims 2 and 4 recite these structural features. Hence, from an objective point of view, the features of the invention can certainly be defined more precisely than in current claim 1 without unduly restricting the scope of protection to which the applicant is justifiably entitled in view of the application as filed taken as a whole. For these reasons, in the present case, the aforementioned conditions expressed in decision T 68/85 for defining the essential technical features of the invention exclusively in terms of functional features are not fulfilled.

3.5 As a consequence, the Board holds that claim 1 of the main request does not clearly define the subject-matter for which protection is sought, contrary to Article 84 EPC.

4. *Auxiliary request I*

Claim 1 of this request contains the additional definition of the force exerted by the ring of muscle tissue of the vagina on the exterior of the housing in relation to the expelling force of the vagina. This definition adds functional features to the claim, but

contains no further structural features of the speculum in order to meet the objection mentioned above.

Consequently, claim 1 of auxiliary request I is likewise not allowable under Article 84 EPC.

5. *Auxiliary request II*

- 5.1 Claim 1 of this request includes also the structural features recited in original dependent claim 2. According to these, the housing part having the U-shaped cross section is "provided with at least one tapering surface that tapers with respect to the longitudinal direction of the speculum in a direction of an external part thereof, on which tapering surface a ring of muscle tissue formed by the musculus sphincter ani externus and/or the musculus bulbocavernosus acts/engages when the speculum is in the position in which it has been inserted in the vagina and is ready for use, such that a compressive force pushing the speculum into the vagina is exerted on said tapering surface for holding said housing part having the U-shaped cross section."

These features clearly specify that the housing has a tapering surface on which muscles of the vagina (i.e. the musculus sphincter ani externus and/or the musculus bulbocavernosus) act or engage such that a compressive force pushing the speculum into the vagina is exerted on the tapering surface. The tapering surface is moreover defined to taper with respect to the longitudinal direction of the speculum in a direction of an external part thereof. Since the compressive force is defined to push the speculum into the vagina, it is clear that the "direction of an external part

thereof (of the speculum)" is to be understood to mean the direction towards the outside of the vagina.

The impugned decision (point 5.4) held that claim 1 should also include, pursuant to Article 84 EPC, the feature of a recess (18) for engagement of the musculus bulbo cavernosus, since this feature had been disclosed in combination with the flat tapering section (17); page 10, lines 22 to 28. The Board disagrees. Original claim 2 provides an appropriately broader definition of the speculum reciting just the tapering surface (with no recess included), and Figures 6 to 8 exemplify such a construction (page 14, lines 1 to 6).

5.2 As claim 1 now includes clear structural features which are essential for obtaining the desired effect of retaining the vaginal speculum in place in the mouth of the vagina when the spoon blades are in a position in which they have been brought together, claim 1 is considered to meet the requirements of Article 84 EPC.

5.3 Moreover, since claim 1 is fairly based on original claims 1 and 2, the requirements of Article 123(2) EPC are likewise met.

5.4 The subject-matter of claim 1 is also novel with respect to document D2 for the following reasons.

D2 discloses a vaginal speculum comprising, in essence, a spoon blade assembly formed by two spoon blades (7, 8), one of which (7) is provided at one end with two bodies (cheeks 9) between which the other one of the spoon blades (8) is hingeably accommodated (column 3, lines 26 to 33; Figure 1), the one spoon blade (7) and its attached cheeks (9) forming a housing. D2 discloses that the blades are provided with recesses (16, 17)

into which the wall of the vagina engages when the blades are moved apart, whereby the speculum achieves a rigid and immovable seat (column 3, lines 51 to 54). The recesses (16, 17) are shown only schematically in Figures 1 and 3.

The housing of the speculum is not disclosed, however, as including a tapering surface as claimed, in particular a tapering surface on which muscles of the vagina, i.e. the musculus sphincter ani externus and/or the musculus bulbocavernosus, may act or engage such that a compressive force pushing the speculum into the vagina may be exerted on the tapering surface when the speculum is in the position in which it has been inserted in the vagina and is ready for use.

As a consequence, the speculum as defined in claim 1 is novel over D2. The requirement of novelty of Article 54(2) EPC is thus fulfilled with respect to D2.

6. The appellant requested the Board to remit the case to the Examining Division if it came to the conclusion that claim 1 of auxiliary request II was clear. After finding that this was the case, the Board found it also necessary to rule on the question of whether claim 1 of auxiliary request II satisfied the requirements of Articles 123(2) and 54(2) EPC with regard to document D2, since the Examining Division had based its decision also on these legal grounds.

The Board does not consider it appropriate, however, to examine itself whether auxiliary request II satisfies all further legal requirements for the grant of a patent, in order not to deprive the appellant of the requested possibility of having these further issues examined by two instances. The case is hence remitted



to the Examining Division for continuation of the examination proceedings on the basis of auxiliary request II (Article 111(1) EPC).

## Order

### For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the department of first instance for further prosecution.

The Registrar:

The Chairman:



D. Hampe

E. Dufrasne

Decision electronically authenticated