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**D E C I S I O N**  
**of 9 January 2003**

**Case Number:** T 1012/01 - 3.2.6

**Application Number:** 91901923.2

**Publication Number:** 0504301

**IPC:** A61F 13/15

**Language of the proceedings:** EN

**Title of invention:**  
Feminine hygiene device

**Applicant:**  
Instead, Inc.

**Opponent:**  
-

**Headword:**  
-

**Relevant legal provisions:**  
EPC Art. 123(2), 54(2), 56, 111(2)

**Keyword:**  
"Amendments (allowable)"  
"Novelty (yes)"  
"Inventive step - after amendment (yes)"  
"Binding effect of an earlier decision of the Board of Appeal  
(reasons, point 2.1)"

**Decisions cited:**  
T 1165/97, T 0153/93

**Catchword:**  
-



Case Number: T 1012/01 - 3.2.6

**D E C I S I O N**  
**of the Technical Board of Appeal 3.2.6**  
**of 9 January 2003**

**Appellant:** Instead, Inc.  
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**Decision under appeal:** Decision of the Examining Division of the  
European Patent Office posted 19 April 2001  
refusing European patent application  
No. 91 901 923.2 pursuant to Article 97(1) EPC.

**Composition of the Board:**

**Chairman:** P. Alting Van Geusau  
**Members:** G. Pricolo  
M. B. Tardo-Dino

## Summary of Facts and Submissions

I. The appeal is from the decision of the Examining Division posted on 19 April 2001 to refuse the European patent application No. 91 901 923.2, filed as PCT/US90/07159 on 7 December 1990 and published on 27 June 1991 under No. WO 91/08779.

II. The Examining Division held that the application as filed did not disclose the feature that the vaginal discharge collector was disposed of after a single use and therefore claim 1 of the main request (filed with letter dated 6 October 2000) did not meet the requirements of Article 123(2) EPC. In respect of the first auxiliary request (filed with letter dated 6 October 2000), the Examining Division held that claim 1 was not novel over the prior art disclosed by document

D5: US-A-2 915 065.

Furthermore, the Examining Division considered that claim 1 of the second auxiliary request (filed with letter dated 6 October 2000) did not meet the requirements of Articles 123(2) and 84 EPC, and that claim 1 of the third auxiliary request (filed with letter dated 9 February 2001) did not involve an inventive step having regard to the disclosure of documents D5 and

D9: US-A-2 616 426.

III. On 18 June 2001 the Appellant (applicant) lodged an appeal against this decision and simultaneously paid the prescribed appeal fee. With the statement setting

out the grounds of appeal, received at the European Patent Office on 10 August 2001, the appellant filed new documents for the grant of a patent according to a main and first to sixth auxiliary requests.

IV. Following a telephone call on 15 November 2001 with the Rapporteur of the Board, the Appellant filed, with letter dated 11 April 2002, a new main request.

V. In an annex to the summons for oral proceedings pursuant to Article 11(2) Rules of Procedure of the Boards of Appeal the Board expressed its preliminary opinion that it would appear that claim 1 of the main request did not meet the requirements of Article 84 EPC because it was not clear whether the reservoir space was part of the collection space or whether these two spaces were separate elements of the vaginal discharge collector. Furthermore, the Board stated that it would appear that the subject-matter of claim 1 lacked an inventive step (Article 56 EPC) in view of the disclosure of document D9. Objections were also raised in respect of the auxiliary requests.

VI. Oral proceedings took place on 9 January 2003.

The appellant requested that the decision under appeal be set aside and a patent granted on the basis of the claims 1 and 2 filed during oral proceedings, with the description and drawings as filed during the oral proceedings.

Claim 1 reads as follows:

"A method of collecting vaginal discharge  
(10;30;40;50;70;80;90;150) comprising the steps of:

(a) providing a vaginal discharge collector including body means (14;34;44;54;74;84;94;154) for providing a collection space (19;29;39;49;59;79;89;99;159) and wherein said collector includes a reservoir space (12;32;42;52;62;72;82;92;152) formed as part of said collection space for the collection of discharge and said collector having an opening for the passage of said discharge into said collection and reservoir spaces, and rim means (11;31;41;51;71;81;91;151) for providing resilient outward holding force sufficient for holding said collector in position within a woman's vaginal canal (201) during use, said body means comprising a top, a generally cup-shaped main wall portion and a bubble-like protrusion, with said generally cup-shaped main wall portion including said top of said body means of said collector, and with said bubble-like protrusion being integrally formed with said generally cup-shaped main wall portion along a generally annular inwardly directed edge, and wherein said generally cup-shaped main wall portion and said bubble-like protrusion form said collection space of said collector, and wherein said bubble-like protrusion forms said reservoir space of said collector, and wherein said bubble-like protrusion is substantially smaller in depth and diameter than said generally cup-shaped wall portion, said rim means having a leading portion and a trailing portion, said rim means being affixed to said body means proximate said top of said body means;

(b) positioning said discharge collector in said position such that said leading portion of said rim means is located at a rearward location (203) behind the woman's cervix (202), such that said trailing portion of said rim means is located at a forward location (204) behind the woman's pelvic bone (205),

and such that the woman's cervix is located between said leading and trailing portions of said rim means;  
(c) holding said collector in said position by applying said resilient outward holding force against the walls of the woman's vaginal canal;  
(d) while holding said collector in said position, collecting said discharge in said collection and reservoir spaces without absorbing said discharge by allowing said discharge to flow through said opening and into said spaces; and  
(e) disposing of said vaginal discharge collector".

VII. In essence, the Appellant's arguments in support of the request are as follows:

Claim 1 was amended to address the clarity objections raised by the Board in the communication accompanying the summons to oral proceedings and now met the requirements of Article 84 EPC.

Its subject-matter also involved an inventive step. Contrary to the Board's opinion expressed in its official communication, D9 did not disclose a generally cup-shaped main wall portion because the apron 12 shown in Figure 1 of D9 was not generally cup-shaped, this expression implying that the main wall portion had the shape of a bowl of a drinking vessel or of a cupped hand. The generally cup-shaped structure of the main wall portion was an important feature of the invention because it provided for a simple and uncomplicated construction of the annular inwardly directed edge. Furthermore, D9 failed to disclose or suggest a bubble-like protrusion substantially smaller in depth and diameter than said generally cup-shaped wall portion. In the context of the D9 disclosure, it made sense that

the cup 10 was deeper than the apron 12 because it was the cup that operated as the pouch to hold the collected fluid and the apron served merely to direct discharge to flow into the cup. In contrast thereto, in the claimed invention fluid was collected in the collection space which **included** the reservoir space. The reservoir space, being visually set off from the larger collection space by the inwardly directed edge, was able to function as a small volume measurement device. It made the product easier to use and more efficient, because it conveniently allowed the user to gauge how much fluid accumulated over a known time period during a certain part of the cycle. This was important because it was easier and less messy to change the product when it was not over full and additionally the user did not want to change the product more often than necessary. Moreover, D9 failed to disclose or suggest the step of disposing of the vaginal collector, since it clearly taught to re-use it after emptying and cleaning.

## **Reasons for the Decision**

1. The appeal is admissible.
2. *Amendments*
  - 2.1 In respect of the present European patent application the Board of Appeal 3.2.6, in a different composition, has already issued decision T 1165/97. In this decision (see point VII, points 2.3 and 5.1) it is stated that claim 1 of the third auxiliary request, which is identical to claim 1 of the main request forming the basis for the decision under appeal in the present

appeal proceedings, did not give rise to objections under Article 123(2) EPC. Therefore, pursuant to Article 111(2) EPC, the Examining Division had no powers to reject claim 1 of the main request for infringement of Article 123(2) EPC as it did, erroneously, in the decision under appeal. Neither is the Board in its present composition empowered to question the above-mentioned finding of the Board of Appeal in the earlier decision T 1165/97 (see eg T 153/93).

In contrast to claim 1 of the third auxiliary request decided upon in T 1165/97 present claim 1 defines, in method step (a), the following additional features of the collector used:

- a reservoir space formed as part of the collection space;
- a generally cup-shaped main wall portion and a bubble-like protrusion, the body means comprising a generally cup-shaped main wall portion and a bubble-like protrusion, with said generally cup-shaped main wall portion including the top of said body means of said collector, and with said bubble-like protrusion being integrally formed with said generally cup-shaped main wall portion along a generally annular inwardly directed edge, and wherein said generally cup-shaped main wall portion and said bubble-like protrusion form said collection space of said collector, and wherein said bubble-like protrusion forms said reservoir space of said collector, and wherein said bubble-like protrusion is substantially smaller in depth and diameter than said generally cup-shaped wall



portion.

Support for the use of a collector having these additional features can be found in original claim 49; on the paragraph bridging pages 11 and 12 of the application as filed; on page 14, second paragraph; and on Figures 1, 2.

Furthermore, claim 1, in step (e) stipulates that the vaginal discharge collector is disposed of, rather than disposed of after a single use as in claim 1 of the third auxiliary request decided upon in T 1165/97. The feature that the collector can be - simply - disposed of, is supported eg by the disclosure on page 7, second paragraph, of the application as filed.

Therefore, on the basis of the previous decision of the Board and on the basis of the cited passages of the application as filed, the compliance of claim 1 with Article 123(2) EPC is to be accepted.

- 2.2 Support for the features of claim 2 is found on page 3, second paragraph, second sentence.
- 2.3 The description was amended to adapt it to the present claims and to cite the documents reflecting the relevant background art.
- 2.4 In view of the above, the amendments to the application do not give rise to objections under Article 123(2) EPC.
- 2.5 The grounds of non-compliance with the requirements of Article 84 EPC given in the communication of the Board accompanying the summons to oral proceedings no longer

apply to claim 1 as amended, since the latter stipulates that the reservoir space is formed as part of the collection space, which corresponds to the disclosure on page 11, last paragraph, of the application as filed, that the collection space includes the reservoir space.

Moreover, since the Board is satisfied that the claims are clear and concise and supported by the description, it concludes that claim 1 meets the requirements of Article 84 EPC.

3. *Novelty*

3.1 Using the wording of claim 1, document D9 discloses a method of collecting vaginal discharge (see column 1, lines 1 to 4) comprising the steps of:

- (a) providing a vaginal discharge collector (see Figure 1) including body means for providing a collection space and wherein said collector includes a reservoir space (11) formed as part of said collection space for the collection of discharge and said collector having an opening for the passage of said discharge into said collection and reservoir spaces, and rim means (13) for providing resilient outward holding force sufficient for holding said collector in position within a woman's vaginal canal (see Figure 2) during use, said body means comprising a top, a generally cup-shaped main wall portion (12) and a bubble-like protrusion (11), with said generally cup-shaped main wall portion including said top of said body means of said collector, and with said bubble-like protrusion being integrally formed

with said generally cup-shaped main wall portion along a generally annular inwardly directed edge, and wherein said generally cup-shaped main wall portion and said bubble-like protrusion form said collection space of said collector, and wherein said bubble-like protrusion forms said reservoir space of said collector, said rim means having a leading portion and a trailing portion, said rim means being affixed to said body means proximate said top of said body means;

- (b) positioning said discharge collector in said position such that said leading portion of said rim means is located at a rearward location behind the woman's cervix, such that said trailing portion of said rim means is located at a forward location behind the woman's pelvic bone, and such that the woman's cervix is located between said leading and trailing portions of said rim means (see Figure 2; column 2, lines 9 to 21);
- (c) holding said collector in said position by applying said resilient outward holding force against the walls of the woman's vaginal canal (see column 2, lines 32 to 35);
- (d) while holding said collector in said position, collecting said discharge in said collection and reservoir spaces without absorbing said discharge by allowing said discharge to flow through said opening and into said spaces (column 1, lines 1 to 4).

D9 does not disclose that the bubble-like protrusion is substantially smaller in depth and diameter than said

generally cup-shaped wall portion, and that the vaginal discharge collector is disposed of. On the contrary, it appears from Figure 1 that the bubble-like protrusion (pouch 11) is greater in depth and also partially greater in diameter than the wall portion (apron 12). Furthermore, D9 discloses (see column 2, lines 36 to 40) that the vaginal collector device is withdrawn, emptied, cleaned and replaced each day during a menstrual period, and is silent about disposal thereof.

- 3.2 The appellant argued that D9 did not disclose a generally cup-shaped main wall portion because the apron 12 shown in Figure 1 of D9 was not generally cup-shaped.

In the Board's view, however, also the frusto-conical apron 12 shown in Figure 1 of D9 (see also column 1, lines 36 to 40) can be designated as generally cup-shaped, because the term "generally" implies that the object in question might be only approximately cup-shaped.

- 3.3 Document D5 discloses a method of collecting vaginal discharge comprising the steps of:

- (a) providing a vaginal discharge collector (Figure 4) including body means (113) for providing a collection space for the collection of discharge and having an opening for the passage of said discharge into said space, and rim means (111) for providing resilient outward holding force sufficient for holding said collector in position within a woman's vaginal canal (Figure 1) during use, said body means having a top and a generally cup-shaped main wall portion (the funnel shaped

portion between the tubular member 113 and the rim 111; see reference 15 in Figure 2), said rim means having a leading portion and a trailing portion, said rim means being affixed to said body means proximate said top of said body means;

- (b) positioning said discharge collector in said position such that said leading portion of said rim means is located at a rearward location behind the woman's cervix, such that said trailing portion of said rim means is located at a forward location behind the woman's pelvic bone, and such that the woman's cervix is located between said leading and trailing portions of said rim means (column 2, lines 52 to 58);
- (c) holding said collector in said position by applying said resilient outward holding force against the walls of the woman's vaginal canal (column 3, lines 3 to 5);
- (d) while holding said collector in said position, collecting said discharge in said collection space without absorbing said discharge by allowing said discharge to flow through said opening and into said space (column 3, lines 6 to 8);
- (e) disposing of said vaginal discharge collector (column 3 lines 13 to 15).

Document D5 does not disclose that the vaginal discharge collector used in the method includes a bubble-like protrusion integrally formed with said generally cup-shaped main wall portion along a generally annular inwardly directed edge, which

protrusion forms a reservoir space of the collector and is substantially smaller in depth and diameter than said generally cup-shaped wall portion.

3.4 The other available documents do not disclose the subject-matter of claim 1. They relate either to contraceptive devices (EP-A-247 837, EP-A-129 271, US-A-4 261 352, DE-C-256 410, DE-C-553 547, US-A-3 169 522), insemination devices (US-A-3 037 508), devices for preventing infections (AU-A-5471/31) or use devices of a different kind for collecting menstrual fluids (DE-C-620 530, AU-B-15818/70).

3.5 It follows that the subject-matter of claim 1 is novel (Article 52(1), 54(2) EPC) over the prior art documents on file.

4. *Inventive step*

4.1 Document D9 represents the closest prior art because it discloses a method having the same general purpose of the method of claim 1 to collect vaginal discharge using a collector (see page 5, last paragraph, of the application as filed) and has the most technical features in common with the claimed method.

The subject-matter of claim 1 is distinguished therefrom in that:

(i) the bubble-like protrusion is substantially smaller in depth and diameter than the generally cup-shaped wall portion, and

(ii) the vaginal discharge collector is disposed of.

4.2 During the proceedings, the applicant submitted that distinguishing feature (i) provides a technical effect in that it allows the user to gauge in a simple and direct manner how much fluid is accumulated over a known time period during a certain part of the cycle. In the Board's view, this effect is indeed obtainable when the method of claim 1 is carried out. Moreover, if the user can predict how much fluid accumulates over a known time period during a certain part of the cycle, the collector can be removed before it is over full, whereby removal thereof becomes easier and less messy.

Distinguishing feature (ii) results in that cleaning of the collector is not necessary.

Therefore, when compared to D9, the objective technical problem solved by the claimed method may be seen in the provision of a method of collecting vaginal discharge using a collector which allows the user to gauge how much vaginal discharge accumulates over a known time period during a certain part of the cycle and which renders unnecessary the cleaning of the collector.

4.3 The available prior art does not disclose the provision of a collector having a bubble-like protrusion which is substantially smaller in volume of the remaining collecting space of the collector (this is inherent in the collector used in the method of claim 1 because the bubble-like protrusion is smaller in depth and diameter than the cup-shaped wall portion), in order to allow the user to gauge how much vaginal discharge accumulates over a known time period.

D9 does not suggest the provision of a bubble-like protrusion which is substantially smaller in volume of

the remaining collecting space of the collector. According to the teaching of D9, the bubble-like protrusion is formed by the pouch or cup 10 which has the function to collect and hold the vaginal discharge (see column 2, lines 13 to 21), whilst apron 12 serves only to direct the discharge into the cup 10. Since it does not serve to hold vaginal discharge, there would be no reason for a skilled person to provide, in the collector of D9, an apron having a volume greater than that of the pouch. D5 does not suggest such modification of the collector of D9, since it clearly teaches the provision of a collecting and holding space (tubular portion 113 in Figure 4) having a volume greater than the funnel shaped collecting portion (15 in Figure 2).

Neither is such modification suggested by the remaining available prior art.

It follows that the subject-matter of claim 1, and of dependent claim 2, is found to involve an inventive step.

## **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 filed during the oral proceedings of 9 January 2003:



**Description:** pages 1, 1a, 2, 2a, 2b, 3 to 28.

**Claims:** 1 and 2.

**Drawings:** sheets 1/3 to 3/3.

The Registrar:

The Chairman:

M. Patin

P. Alting van Geusau