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D E C I S I O N
of 15 February 2000

Case Number: T 1165/97 - 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:
Ultrafem, Inc.

Opponent:
-

Headword:
Feminine hygiene device/ULTRAFEM INC.

Relevant legal provisions:
EPC Art. 52(1), (4), 57, 123(2)

Keyword:
"Industrial application of a method of collecting and
disposing of vaginal discharge (yes)"
"Amendments -added subject-matter (yes)"

Decisions cited:
T 0074/93, T 0144/83, T 0385/86

Catchword:
A method of placing a vaginal discharge collector, holding it

in place in the vaginal canal of a woman, collecting discharge in the collector, retrieving it and disposing of the collector after a single use can be considered susceptible of industrial application if it is imaginable that these steps are carried out as a paid service and are not exclusively dependent for their execution on the instructions of the woman in question. (points 3.1 and 3.2)



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Boards of Appeal

Chambres de recours

Case Number: T 1165/97 - 3.2.6

D E C I S I O N
of the Technical Board of Appeal 3.2.6
of 15 February 2000

Appellant: Ultrafem, Inc.
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Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 18 July 1997
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: H. Meinders
C. Holtz

Summary of Facts and Submissions

- I. European patent application No. 91 901 923.2 published under No. 0 504 301 was refused by the Examining Division by decision dated 18 July 1997.
- II. The basis for the decision of the Examining Division consisted of a main request and three auxiliary requests. The reasons given for the refusal was that the subject-matter of claim 1 of the main and first auxiliary request (relating to a method of using a vaginal discharge collector, now claims 1 and 8 of the third auxiliary request and claim 1 of the fourth auxiliary request) did not comply with the requirement of industrial applicability (Article 57 EPC).

It based its argumentation primarily on decision T 74/93 (OJ EPO 1995, 712) which considered a method of contraception which was to be applied in the private and personal sphere of a human being as not being susceptible of industrial application (see Headnote).

It argued that even if the positioning was done by somebody else than the person in question, eg a nurse or a doctor, this activity would fall under the exception of Article 52(4) EPC (methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body), rendering the subject-matter of the claim already unpatentable for that reason alone. In addition, the steps of holding it in place and collecting the vaginal discharge were individually and personally performed by the woman in question and an industrial application of such a step could not be

imagined. Finally, the step of disposing the discharge collector had no relation to an industrial applicability.

The subject-matter of claim 1 of the second and third auxiliary request (relating to a set of vaginal discharge collectors) was considered to lack inventive step (Article 56 EPC) in respect of each of the following documents on its own:

D1: EP-A-0 247 837,

D2: EP-A-0 129 271,

D3: US-A-2 915 065,

the features distinguishing the claim over each of these documents being considered as not adding technical details to the collector itself, but relating to the way the collector was sold.

III. On 18 September 1997 the Appellant (applicant) lodged an appeal against this decision and paid the prescribed appeal fee. On 14 November 1997 a statement of grounds of appeal was filed.

IV. The Appellant requests cancellation of the decision and grant on the basis of the main request considered by the Examining Division or auxiliarily on the basis of one of four auxiliary requests. Auxiliarily oral proceedings were requested.

In essence, the Appellant's arguments in support of the appeal are as follows:

The Examining Division applied Article 57 EPC in a too narrow and restrictive manner. Article 57 EPC did not state that an invention which was normally carried out in private circumstances was not susceptible of industrial application, what counts was whether the method was capable of being used in **any** kind of industry. The method of the invention is equivalent to a method of collection and disposal of waste products; a company **could** run a business supplying and disposing of the collectors in question.

In respect of decision T 74/93 (supra) the Appellant argued that the present case was different, as the major reasons for the person for performing the method of the invention were not private but either cosmetic (maintaining the personal appearance, prevention of odours, preventing tell-tale signs of menstruation) or professional (being capable of continued carrying out of certain professions). More applicable than the above decision would be the decision T 144/83 (OJ EPO 1986, 301) relating to a method of orally administering naltrexone and continuing to do so until a cosmetically beneficial loss of weight has occurred. In both cases the actual physical steps were carried out in private by the person employing the method, under instructions of a third party with a commercial interest in the use of the method (in the case of T 144/83 the supplier of naltrexone, in the present case the supplier of the discharge collectors).

- V. In a communication accompanying summons for oral proceedings pursuant to Article 11(2) of the Rules of Procedure of the Boards of Appeal the Board expressed the preliminary opinion that the main, first and second

auxiliary request (comprising claims to the set of vaginal discharge collectors) were in conflict with Article 123(2) EPC for adding subject-matter to the application which was not originally disclosed. The third and fourth auxiliary request (with only claims to a method of using a vaginal discharge collector) were considered to fulfil the requirement of industrial applicability. The Board indicated its intention to refuse the main, first and second auxiliary request and refer the case back to the Examining Division for prosecution of the examination in respect of novelty and inventive step on the basis of the claims of the third and fourth auxiliary requests, the reasons for refusal of these claims no longer being applicable. If the applicant agreed, oral proceedings could be avoided.

VI. By facsimile letter of 11 January 2000 the applicant agreed to this procedure requesting cancellation of the oral proceedings, which was ordered by the Board that same day.

VII. Relevant for this decision are the following claims:

Claim 9 of the main request:

"A set of vaginal discharge collectors (10; 20; 30; 40; 50; 60; 70; 80; 90; 100; 110; 120; 130; 140; 150), each of said collectors comprising:

body means (14; 24; 34; 44; 54; 64; 74; 84; 94; 104; 114; 124; 134; 144; 154) for providing a collection space (19; 29; 39; 49; 59; 69; 79; 89; 99; 159) for the collection of discharge and having an opening for the passage of discharge into said space;

rim means (11; 21; 31; 41; 51; 61; 71; 81; 91; 121; 141; 151) for providing resilient outward holding force sufficient for holding the collector in position during use, said rim means being affixed to said body means proximate the top of said body means; wherein said collectors are located together to be used and disposed of seriatim by a user during a single period of menstruation and wherein the rim means of each collector is a solid annulus formed entirely of elastomeric material."

Claims 8 and 1 of the first and second auxiliary requests respectively:

The sole difference between these claims and claim 9 of the main request as set out above resides in the fact that the feature of the rim means being "a solid annulus formed entirely of elastomeric material" was transferred from the last line of the claim to the location after "rim means (11; 21; 31; 41; 51; 61; 71; 81; 91; 121; 141; 151)".

Claim 1 of the third auxiliary request:

"A method of using a vaginal discharge collector (10; 20; 30; 40; 50; 60; 70; 80; 90; 100; 110; 120; 130; 140; 150) comprising the steps of:

- (a) providing a vaginal discharge collector including body means (14; 24; 34; 44; 54; 64; 74; 84; 94; 104; 114; 124; 134; 144; 154) for providing a collection space (19; 29; 39; 49; 59; 69; 79; 89; 99; 159) for the collection of discharge and having an opening for the passage of said

discharge into said space, and rim means (11; 21; 31; 41; 51; 61; 71; 81; 91; 121; 141; 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 having a top, 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 space without absorbing said discharge by allowing said discharge to flow through said opening and into said space; and
- (e) subsequently, disposing of said vaginal discharge collector after a single use."

Claim 1 of the fourth auxiliary request:

Differs from claim 1 of the third auxiliary request solely in that:

"A method of collecting and disposing of vaginal discharge (10; 20; 30; 40; 50; 60; 70; 80; 90; 100; 110; 120; 130; 140; 150) comprising the steps of:" replaces:

"A method of using a vaginal discharge collector (10; 20; 30; 40; 50; 60; 70; 80; 90; 100; 110; 120; 130; 140; 150) comprising the steps of:".

Claim 8 of the third auxiliary request:

"A method of collecting vaginal discharge using a vaginal discharge collector (10; 20; 30; 40; 50; 60; 70; 80; 90; 100; 110; 120; 130; 140; 150) including body means (14; 24; 34; 44; 54; 64; 74; 84; 94; 104; 114; 124; 134; 144; 154) for providing a collection space (19; 29; 39; 49; 59; 69; 79; 89; 99; 159) for the collection of discharge and having an opening for the passage of said discharge into said space, and rim means (11; 21; 31; 41; 51; 61; 71; 81; 91; 121; 141; 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 having a top, 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 comprising the steps of:

- (a) collecting said discharge in said collection space without absorbing said discharge by allowing said discharge to flow through said opening and into

said space; and

(b) subsequently, disposing of said vaginal discharge collector after a single use."

Reasons for the decision

1. The appeal is admissible.

2. *Amendments (Article 123(2) EPC)*

2.1 When introducing the claims relating to a "set" of vaginal discharge collectors into the application during the examination proceedings, with letter of 9 April 1996, the Applicant referred as support therefor to page 3, lines 26 to 28 and page 7, lines 5 to 9 of the originally filed application documents. However, these references do not disclose or otherwise support the claimed set of vaginal collectors as referred to above for the following reasons:

The mention to the fact that the collectors are "disposable", does not allow the conclusion that they are intended to be disposed of "seriatim". As regards the word "seriatim": the original application documents do not mention that after taking one collector out of the vagina, it should be substituted by another from a series.

The mention on page 1 of the original application documents that the collectors are considered to be an alternative to sanitary napkins or tampons does not

allow the conclusion either that the collectors are "located together in a set". Firstly, on this page the napkins or tampons themselves are not referred to in connection with them being packaged together, let alone being "located together in a set". Secondly, napkins and tampons are not packed together to be used and disposed of "in a single period of menstruation". As with diapers, they can be bought in small or large quantity packages; no mention is made on the package that the contents are for use in one single period of menstruation only.

Further, the mention on page 14, lines 21 to 23 of the original application documents relates only to the possible volume of the collector, which cannot imply a "set" of collectors as such. The mention on page 26, lines 21 to 26 relates to the possibility of a larger volume of the collector, such that it can be worn for a longer time or when larger quantities of discharge are to be expected. Also this disclosure cannot be considered as implying a "set" of collectors.

2.2 Therefore, since no support is to be found in the originally filed application for the disclosure of a plurality of vaginal discharge collectors being "located together in a set to be used and disposed of seriatim by a user during a single period of menstruation", the independent claim 9 of the main request and claims 8 and 1 of the first and second auxiliary requests respectively, contravene the requirements of Article 123(2) EPC. As a consequence these requests are not allowable.

2.3 Support for the subject-matter of the independent

claims of the third and fourth auxiliary request can be found on page 23, first paragraph and claim 65. Page 6, fourth paragraph and page 19, penultimate sentence contain the information that the absorption of the discharge may be dispensed with.

3. *Requirement of industrial applicability (Article 57 EPC)*

- 3.1 It is the view of the Board that the method as claimed by the above mentioned independent claims of the third and fourth auxiliary request complies with the requirements of Article 57 EPC, which consider an invention as susceptible of industrial application if it can be made or used in any kind of industry.

Such a method can be performed by an enterprise of which the object is to assist women in collecting a sample of their vaginal discharge, eg for subsequent visual, chemical or bacterial inspection or for extraction of one or more of its components for use in industrial preparation of pharmaceutical compositions. Whether such enterprises actually exist is not relevant for the purposes of Article 57 EPC, what counts is the possibility that such a service may be offered by an enterprise. For the question whether the method of collecting a sample under the exclusion of diagnostical methods pursuant to Article 52(4) EPC, see point 4.3 below.

At present there exist (hospital-)laboratories offering the service of taking samples of body fluids (eg blood, sputum, mucus) for further analysis. Such services are performed for a fee and are run on a commercial basis. They perform their functions "continually, independently and for financial gain" (see decision T 144/83, supra, Reasons point 5). It is not inconceivable that such services are extended to the provision and placement of a vaginal discharge collector, collection of vaginal discharge therein and the retrieval and subsequent disposal of the collector as presently claimed in the method claims of the third and fourth auxiliary request.

- 3.2 In decision T 74/93 (cf supra) relied upon by the Examining Division the Board considered that a method of contraception which was to be applied in the private and personal sphere of the woman in question was not susceptible of industrial application. The Board considered that apart from the exception of industrial applicability enshrined in Article 52(4) EPC an invention still had to comply with the requirements of Article 57 EPC.

In one example it was discussed whether the fact that a nurse could be applying the method to a disabled person was sufficient to fulfil the requirement of industrial applicability. The Board deciding case T 74/93 considered that the fact that such a nurse acts professionally did not suffice to make the application of the method an industrial activity. The service of applying the contraceptive method was not offered as an industry but to satisfy the strictly personal needs of the disabled person. It followed therefrom that the

nature of the activity was not changed by the fact that it was not exercised by the disabled person in question, but by her assistant following her instructions.

In the present case, it can be foreseen that application and retrieval of the discharge collector is performed by a professional in the service of an enterprise. However, in contrast to the case of decision T 74/93, this service is not one satisfying only the strictly personal needs of the woman in question. Collecting a sample may be caused by external reasons, eg the advice of a medical practitioner to have such a sample taken for further diagnosis. Moreover, in the situation described above, the person taking the sample will generally not be acting on the instructions of the woman in question, but rather on the basis of the instructions supplied with the collector itself, if necessary supplemented by instructions issued by his/her superior.

4. *Exclusion under Article 52(4) EPC*

4.1 As far as the aspect of industrial applicability is concerned it is, however, also necessary to examine whether the exclusion of industrial applicability under Article 52(4) EPC applies.

4.2 In the present case that is not so. The mere placement in and collection of the discharge device in the vaginal canal of a female, even if performed by a medically trained person or a doctor, is not a method of treatment of the human or animal body by surgery or therapy. A prerequisite therefor is the act of surgery

or the curative or preventive treatment of illness or the alleviation of the symptoms of pain and suffering, which is not the case with the method of the invention. Neither is there the necessity of particular medical skills in positioning and removing the discharge collector, as these actions are identical to the placement and removal of a contraceptive device such as a pessary, which is performed by women themselves.

- 4.3 Neither is there a case of a diagnostic method practised on the human or animal body, since that exclusion only applies to diagnostic methods of which the results make it directly possible to decide on a particular course of medical treatment. To fall under this exclusion the method claimed should contain all the steps involved in reaching a medical diagnosis. The steps of providing a collector, placing it, collecting discharge therein, retrieving and disposing of it do not fulfil this condition because on the sample thus collected not even data are gathered (see decision T 385/86, OJ EPO 1988, 308).

However, in this respect it must be guaranteed that all references to methods of therapeutical treatment are deleted from the description. See eg page 4, second and fourth paragraph; page 5, first and second paragraph; the paragraph bridging pages 6 and 7; page 13, second paragraph, fifth sentence; page 20, line 5; page 28, second paragraph.

5. *Procedural considerations*

- 5.1 For the reasons explained above the independent claims 1 and 8 in accordance with the third auxiliary

request do not give rise to objections with respect to added subject-matter or industrial applicability.

Claim 1 of the fourth auxiliary request is practically identical to claim 1 of the third auxiliary request and also fulfils these requirements.

However, these method claims have not yet been examined by the Examining Division with respect to novelty and inventive step. In conformity with the case law of the Boards of Appeal, such a case is normally referred back to the Examining Division for further prosecution. Thus the Board decides to make use of its powers pursuant to Article 111(1), second sentence EPC to refer the case back to the Examining Division for further prosecution, particularly in view of the explicit request made by the applicant to that effect.

- 5.2 In this respect the Board wishes to point at documents D5 (US-A-2 915 065) and D9 (US-A-2 616 426) which appear to represent more relevant prior art for the vaginal discharge collector and its technical features as claimed in the present method claims than that disclosed in D1-D3 considered in the decision under appeal.

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 for further

prosecution.

The Registrar:

The Chairman:

M. Patin

P. Alting van Geusau