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D E C I S I O N
of 27 November 2003

Case Number: T 1204/01 - 3.2.6

Application Number: 95108388.0

Publication Number: 0685215

IPC: A61F 13/20

Language of the proceedings: EN

Title of invention:

Vaginal moisture balanced tampon and process

Applicant:

McNEIL-PPC, INC.

Opponent:

-

Headword:

-

Relevant legal provisions:

EPC Art. 84

Keyword:

"Support in description (no)"

Decisions cited:

T 0593/96, T 0409/91

Catchword:

-



Case Number: T 1204/01 - 3.2.6

D E C I S I O N
of the Technical Board of Appeal 3.2.6
of 27 November 2003

Appellant: McNEILL-PPC, INC.
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Representative: Groening, Hans Wilhelm, Dipl.-Ing.
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Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 6 June 2001
refusing European application No. 95108388.0
pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: P. Alting van Geusau
Members: H. Meinders
M. B. Tardo-Dino

Summary of Facts and Submissions

- I. European patent application 95 108 388.0 was refused by the Examining Division by decision posted 6 June 2001.
- II. The reason given for the refusal was that the subject-matter of claim 1 filed with letter of 27 April 2001 did not involve inventive step. It referred in its decision to the following documents:

D1: EP-A-0 546 256

D2: WO-A-9 002 542

D3: WO-A-9 006 737.

In the European Search Report made up on the present application reference was made to:

D7: US-A-4 335 722.

- III. On 13 August 2001 the Appellant (Applicant) lodged an appeal against this decision and paid the prescribed appeal fee that same day. It requested grant of a patent with claim 1 as rejected by the Examining Division. On 15 October 2001 a statement of grounds of appeal was filed, with an auxiliary request.
- IV. With the summons to oral proceedings the Board expressed its provisional opinion that formal objections pursuant to Article 84 EPC (clarity and support in the description) existed against claim 1 as requested according to the main and the auxiliary request of the Appellant. In particular it found that

support was lacking for any embodiments covered by the wording of claim 1 which did **not** involve a tampon with an absorbent core and a cover exclusively made of hydrophobic fibers surrounding the core (see point VI for the wording of the claims).

V. Oral proceedings were held on 27 November 2003, in which the Appellant requested grant of a patent according to its main request filed with letter of 19 November 2003 or one of two auxiliary requests filed in the oral proceedings before the Board.

VI. Claim 1 according to the **main request** reads as follows:

"An absorbent tampon comprising an absorbent core having a hydrophilic material and a hydrophobic material, characterized in that the absorbent core comprises a combination of hydrophilic fibers and hydrophobic fibers, with 10 to 90% of the absorbent core fibers being hydrophobic fibers which are effective to provide a tampon having an initial surface capillary suction pressure of less than 40 mm Hg measured by the reduction in pressure in a column of liquid behind a porous plate when the absorbent tampon is brought into contact with the porous plate."

Claim 1 according to the **first auxiliary request** reads as follows:

"An absorbent tampon comprising an absorbent core having a hydrophilic material and a hydrophobic material, characterized in that the absorbent core has a density of less than 0.25 g/cc, is made from fibers with at least 0.33 tex and comprises a combination of

hydrophilic fibers and hydrophobic fibers, which are effective to provide a tampon having an initial surface capillary suction pressure of less than 40 mm Hg measured by the reduction in pressure in a column of liquid behind a porous plate when the absorbent tampon is brought into contact with the porous plate."

Claim 1 according to the **second auxiliary request** reads as follows:

"An absorbent tampon having a low initial surface capillary suction pressure comprising an absorbent core and means for removing the tampon after use of the absorbent core, the absorbent core has a density of less than 0.25 g/cc, the absorbent core is made from fibers with at least 0.33 tex, and the absorbent core comprises a combination of hydrophilic fibers and hydrophobic fibers."

VII. The arguments of the Appellant can be summarized as follows:

Main request:

The Appellant was not interested in limiting the subject-matter of claim 1 to a tampon having a core surrounded by a cover of hydrophobic fibers, which found support in the description of the application as suggested by the Board, as it had already obtained a patent granted for that subject-matter on a divisional application of the present application. For the present application it did not wish to limit itself to that embodiment, but to also cover embodiments which achieved the low initial surface capillary suction

pressure by mixing certain amounts of hydrophobic fibers with hydrophilic fibers, by changing the denier of the fibers or by changing the density of the absorbent core.

Support for the tampon as now claimed, i.e. **not** limited to a core with a cover, could be found on page 10, line 4 to page 11, line 14 of the application as filed. These passages discussed the possibility to change the relationship between hydrophilic and hydrophobic fibers in the core, the denier of the fibers and the density of the tampon as separate or as combinable possibilities.

The same applied to table 6, where certain of the tested products had different compositions (either 100% rayon or a 50-50 mixture of rayon and polyester) and different densities (0.19 to 0.43 g/cc). Finally, from page 20, lines 25 to 37 discussing the graph of figure 2, it could be derived from the *in vivo* tests that there was a correlation coefficient equal to 0.65 for the initial surface capillary suction pressure of 40 mm. These indications would support a claim which was not limited to a core with a hydrophobic cover.

First auxiliary request:

For this request the same arguments applied. The 0.33 tex for the fibers was disclosed as the minimum of 3 denier fibers necessary for the core on page 10, line 24 and claim 11 as originally filed; the density of less than 0.25 g/cc followed from page 10, line 34 and claim 24 as originally filed.

Second auxiliary request:

This request should be allowed into the proceedings at this late stage, as it was a reply to the objections made by the Board and it found its basis in claim 11 ("The tampon of claim 10 wherein the absorbent core comprises synthetic fibers having a denier of at least about 3") and claim 24 ("Method of producing a tampon having low surface capillary suction pressure comprising the steps of: a) forming an absorbent core having a density of less than 0.25 g/cc; and b) attaching means for removing the tampon after use of the absorbent core").

Reasons for the Decision

1. The appeal is admissible.
2. *Support in the description (Article 84 EPC) - Main request*

In the annex to the summons to oral proceedings the Board had objected to lack of support in the description for the feature in claim 1 of the main request of the initial surface capillary suction pressure of 40 mm Hg in respect of tampons **not** having a hydrophobic fiber cover on an absorbent core.

- 2.1 The Appellant argued in the oral proceedings that the fact that the absorbent core fibres were 10 to 90% hydrophobic fibres as claimed and disclosed on page 10 as originally filed already resulted in the claimed suction pressure of 40 mm Hg.

For the Board this disclosure, however, cannot provide the required support as it is in itself unclear: it does not clearly define the amount of fibres because it lacks a reference to the weight or the volume.

Furthermore, only the products D, E and F actually tested provide an initial surface capillary suction pressure below 40 mm Hg. However, **all** these products had a hydrophobic fibre cover on an absorbent core, thus the claimed suction pressure effect is not disclosed as being exclusively linked to the proportion of hydrophobic to hydrophilic fibres.

Finally, of the products tested, product D had 100% rayon and products E and F had a 50%-50% mixture of rayon-polyester fibres. Apart from the fact that, again, these percentages are not mentioned as being by weight or by volume, such a limited amount (2) of different test products, with only 100% or 50-50% cannot provide a proper basis for the wide range of 10 to 90% as claimed. This is even more so since the amount of fibres was not the only parameter tested with these products, but also the number and type of cover layer(s) (product D: 8 layers and product E: 1 layer, product F: cover layer of product B), the density (three different densities for the products D, E and F) and the denier of the fibres in the core (product D: no mention, products E and F: 3 denier rayon with 5.5 denier polyester). Thus the effect on the suction pressure cannot exclusively be attributed to the composition of the absorbent core.

2.2 The appellant argued that the references on page 10 and 11 of the description as filed, referring to the possibility to use different compositions, different denier fibres and different densities provided sufficient support for present claim 1.

The Board agrees with the appellant that these possibilities have been originally disclosed, thus the requirements of Article 123(2) EPC would be fulfilled. However, the present issue is not one of extension of subject-matter, it is the question whether the subject-matter of claim 1 is **adequately supported** by the description (Article 84 EPC).

2.3 In that respect the Board cannot, however, agree with the Appellant's view that there is adequate support for present claim 1, as the scope of the patent monopoly should correspond to the applicant's contribution to the art (see e.g. T 409/91, OJ 1994, 653, point 3.3 of the Reasons).

In the present case the contribution to the art is, according to this Board, what the patent in suit discloses as tampons actually fulfilling the parameter condition claimed, i.e. the initial surface capillary suction pressure of less than 40 mm Hg as determined by the test procedure disclosed in the application. The three products fulfilling those requirements have one feature in common, namely the presence of a hydrophobic fiber cover on the absorbent core. There are no test results available for other products fulfilling the suction pressure requirement, thus the skilled person is not provided with an enabling disclosure on how to

achieve the claimed suction pressure with products **not** having such a cover.

Furthermore, the part of the description cited by the Appellant as forming the basis for the presently claimed products (pages 10 and 11) is not related to the presently claimed "at least 40 mm Hg". In fact, no value whatsoever is mentioned for this suction pressure.

- 2.4 It could be argued that in formulating the claims, the applicant should be able to do so in terms as broad as possible, as most claims are generalizations of one or more particular examples.

In this respect the Board finds that the extent of generalization depends on what is the actual extent of the patent's contribution to the state of the art. In this context the Board supports the idea that, as the Guidelines for Examination in the EPO suggest (C-III, 6.2): "An invention which opens up a whole new field is entitled to more generality in the claims than one which is concerned with advances in a known technology. In particular, if it is reasonable to predict that all the variants covered by the claims have the properties or uses the applicant ascribes to them in the description, he should be allowed to draw his claims accordingly." (see also T 593/96, not published, point 5 of the Reasons).

However, the Board cannot see that the present invention "opens up a whole new field of technology", as the prevention of the drying of the vaginal epithelium tissue is a topic which has already been

discussed before in this field. Relevant prior art like D2 mentions this problem (page 5, lines 1 to 3) and tries to solve it by coating an otherwise conventional tampon like the o.b., tampax, playtex or kotex tampons (see page 6, first paragraph) with a beeswax coating of between 10 and 50 mils thickness (page 6, second paragraph). These conventional products are also the comparative products for the tests performed for the present application. According to the test performed by the applicant on such a tampon covered with 22 mils of beeswax, of which the results were filed with letter of 31 August 2000, an initial surface capillary suction pressure of 48.3 and 58.4 mm Hg was already achieved.

Also in D7, column 1, lines 17 to 28 this problem is discussed, in particular in relation to rapid uptake of fluid by the tampon resulting in suction forces on the vaginal wall, which requires physical force on withdrawal of the tampon, thus epithelial damage could result.

2.5 The Applicant finally argued that on the basis of the graph in figure 2 (based on the data of table 6) it was concluded there was a correlation coefficient of 0.65 for 40 mm Hg, thus proving that the 40 mm Hg was a threshold value, independent of how the core of the tampon was composed.

The Board cannot subscribe to this opinion, because the points in the graph of figure 2 are based on the tested products as referred to in table 6, of which only products D, E and F fulfill the requirement of less than 40 mm Hg suction pressure. However, exactly these

products have a hydrophobic fiber cover on the absorbent core.

- 2.6 For the Board the contribution of the patent application to the state of the art, in connection with the composition of the absorbent core of the tampon comprising hydrophilic and hydrophobic fibers is thus limited to what has been disclosed for the tested products D, E and F, which, however, involve a tampon with at least an absorbent core and a hydrophobic fiber cover.

Claim 1 of the main request therefore does not fulfill the requirements of Article 84 EPC. This request is therefore to be refused.

3. *Support in the description (Article 84 EPC) - first auxiliary request*

- 3.1 The arguments brought forward against the main request equally apply to claim 1 according to the first auxiliary request. The amendment consisting of the value of the density not being greater than 0.25 g/cc is referred to in the same passage, namely page 10, lines 32 to 35, as mentioned for the different other possibilities influencing the capillary suction pressure. For the density there is no relationship mentioned with the specific value of 40 mm Hg suction pressure. Again, the only basis is found in table 6, where two densities lower than 0.25 g/cc were present in tested products achieving a suction pressure of less than 40 mm Hg. However, here again these products had an absorbent core with a hydrophobic fiber cover (products E and F).

- 3.2 With respect to the amendment consisting of the added feature of the fibers being at least 3 denier (0.33 tex) the above objections apply as well.

Thus the contribution of the patent application to the state of the art, in connection with the density of the core, the denier of the fibers and the 40 mm Hg suction pressure is limited to what has been disclosed for the tested products E and F, which, however, involve a tampon with at least an absorbent core and a hydrophobic fiber cover.

Claim 1 of the first auxiliary request therefore does not fulfill the requirements of Article 84 EPC and is therefore to be refused.

4. *Second auxiliary request - admissibility*

- 4.1 The Appellant argued that claim 1 of the second auxiliary request, filed in the oral proceedings before the Board, should be admitted at this late stage of the proceedings as it was based on claims 11 and 24 of the application as originally filed, thus there was no shift in the subject-matter of the application as filed. Further, it was filed in reply to the objections made by the Board in the oral proceedings.

- 4.2 The Board wishes to note that the objections made by it in the oral proceedings were the same objections raised in the annex to the summons to oral proceedings, namely the question of clarity and support in the description for claim 1 relating to a tampon having a surface capillary suction pressure of less than 40 mm Hg. Thus

the Appellant was aware of these objections well in advance of the oral proceedings, but chose not to file the present second auxiliary request as a reply to these objections, even though it was able to propose other amendments as an auxiliary request with its letter of 19 November 2003.

Thus this request is filed without sufficient reason for its late filing.

- 4.3 In the examination proceedings claim 24 relating to the method of producing a tampon with at least 0.25 g/cc density and having low surface capillary suction pressure was objected to for lack of clarity by the Examining Division and was no longer pursued in those proceedings by the Appellant.

Product claim 1 as examined by the Examining Division involving 6 communications, and in the decision under appeal, consistently claimed the feature of the (initial) surface capillary suction pressure expressed in the parameter value of 40 mm Hg.

- 4.4 Product claim 1 as per the second auxiliary request does not comprise this parameter value and claims a "low initial surface capillary suction pressure" only in connection with a density of less than 0.25 g/cc, the denier of the fibres being at least 0.33 tex and the core comprising a combination of hydrophilic and hydrophobic fibres.

The Board can only conclude from the above that there is a complete shift in the subject-matter claimed, outside of the scope of the preceding examination- and

examination appeal proceedings and of the decision under appeal. Further, it amounts to reverting back to a broader claim which had no longer been pursued in examination and against which objections pursuant to Article 84 EPC had already been raised at an early stage of the examination proceedings.

- 4.5 According to Article 111(1) EPC, second sentence, the Board may either exercise any power within the competence of the department which was responsible for the decision appealed or remit the case to that department for further prosecution.

According to Rule 86(3) EPC the Examining Division has the discretion to consent to further amendments of the application, subsequent to those following receipt of the first communication by the Examining Division.

In view of the fact that the examination proceedings from the first communication dated 11 June 1997 to the decision under appeal of 6 June 2001 have taken all of four years and 6 communications, the Board considers it appropriate to exercise itself the powers of the Examining Division pursuant to Rule 86(3) EPC, so as to bring the matter to a close.

In view of the fact that the second auxiliary request was filed late without sufficient reasons for its delay and completely shifts the issue away from the issue upon which the decision under appeal was taken, necessitating a complete examination from the beginning, in application of Rule 86(3) EPC, the Board does not admit the second auxiliary request to the appeal proceedings.

4.6 No allowable requests being available, the appeal is to be dismissed.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

M. Patin

P. Alting van Geusau