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D E C I S I O N
of 22 June 2006

Case Number: T 0513/04 - 3.3.10

Application Number: 98920707.1

Publication Number: 0988066

IPC: A61L 15/26

Language of the proceedings: EN

Title of invention:

Absorbent interlabial device treated with a polysiloxane emollient

Applicant:

THE PROCTER & GAMBLE COMPANY

Opponent:

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Headword:

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Relevant legal provisions:

EPC Art. 56, 111(1)

Keyword:

"Inventive step (no): main request - redefinition of technical problem - obvious solution"

"Remittal (yes): first auxiliary request - fresh case"

Decisions cited:

G 0010/93, T 0020/81, T 0063/86, T 0047/90

Catchword:

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Case Number: T 0513/04 - 3.3.10

D E C I S I O N
of the Technical Board of Appeal 3.3.10
of 22 June 2006

Appellant: THE PROCTER & GAMBLE COMPANY
One Procter & Gamble Plaza
Cincinnati, Ohio 45202 (US)

Representative: Kremer, Véronique Marie Joséphine
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Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 8 October 2003
refusing European application No. 98920707.1
pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: R. Freimuth
Members: P. Gryczka
D. Rogers

Summary of Facts and Submissions

I. The present appeal lies from the decision of the Examining Division posted on 8 October 2003 refusing the European patent application No. 98 920 707.1 published under the International publication No. WO 98/55158.

II. The decision under appeal was based on claims 1 to 10 submitted by the Applicant with a letter dated 12 September 2002. Claim 1 read as follows:

"1. An absorbent interlabial device (20) for wearing in the interlabial space of a female wearer said interlabial device having a body-contacting surface (20A) at least a portion of which is capable of maintaining contact with the inside surfaces of the wearer's labia when said device (20) is worn, and an absorbent portion (22), characterized in that at least a portion of said body-contacting surface (20A) comprises an effective amount of a polysiloxane emollient composition, said emollient composition comprising a substantially water free polysiloxane emollient having a plastic or fluid consistency at 20°C."

Claims 2 to 10 were dependent on claim 1.

III. The Examining Division held that the claimed subject-matter did not involve an inventive step when considering the teaching of document

(1) WO-A-96/16681.

The claimed absorbent device differed from the device disclosed in document (1) only in that it was defined as an "interlabial" device. Document (1) concerned absorbent articles such as diapers, training pants, adult incontinence devices and the like and thus belonged to the same technical field as the patent application. In addition, document (1) taught to provide the absorbent article with a top sheet coated with the same lotion as that of the present invention.

- IV. With letter dated 5 May 2006, the Appellant filed two amended set of claims as first and second auxiliary requests.

Claim 1 of the first auxiliary differed from claim 1 underlying the decision under appeal by the addition at the end of the claim of the expression "wherein said absorbent device is sufficiently flushable that it completely clears the bowl under the flushability test at least 70% of the time in two or fewer flushes."

- V. Oral proceedings took place on 22 June 2006 before the Board.

- VI. The Appellant argued that the interlabial devices in accordance with the documents acknowledged in the introductory part of the description of the patent application should be considered as the closest prior art. The problem underlying the present invention was to provide an absorbent interlabial device which reduced friction associated with rubbing of the device against the labial wall and sticking to said walls and which had no tendency to dry the wearer's labia. This problem was solved by the claimed emollient-treated

interlabial device. Document (1) concerned diapers which were intended to be used on normal skin but not in the interlabial environment. The specific problems linked to labia which were formed by sensitive mucous membranes and had a tendency to dry out did not occur with normal skin. In addition diapers did not extend between the labia and were relatively thick to absorb high quantities of urine and, thus, were not suitable from an anatomical point of view to be carried between the female labia. Therefore, the skilled person would not even consider the teaching of document (1) when trying to solve problems linked to the use of interlabial devices and, in any case, would not get from that remote prior art any pointer to the claimed interlabial article. Applying the teaching of document (1) to interlabial devices could only result from an *ex post facto* analysis of the prior art. Thus, the claimed subject-matter involved an inventive step.

VII. The Appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of claims 1 to 10 submitted with the letter dated 12 September 2002 (main request), alternatively on the basis of claims 1 to 10 of the first or the second auxiliary request filed with the letter dated 5 May 2006.

VIII. At the end of the oral proceedings the decision of the Board was announced.

Reasons for the Decision

1. The appeal is admissible.

Main request

2. It was not contested in the decision under appeal that the claims in accordance with the main request find a basis in the application as filed, were clear and that they define novel subject-matter (Articles 123(2), 84 and 54 EPC). In view of the negative outcome with respect to the issue of inventive step in the appeal proceedings, it is unnecessary to go into more detail with respect to those issues.

3. *Inventive step*
 - 3.1 For the assessment of inventive step in accordance with the "problem-solution approach", it is necessary to establish the closest prior art in order to determine in the light thereof the technical problem which the invention addresses and solves. The "closest prior art" is normally represented by a prior art document disclosing subject-matter aiming at the same objective as the claimed invention and having the most relevant technical features in common (Case Law of the Boards of Appeal of the EPO, 4th. Edition 2001, I.D.3.1).

 - 3.2 The patent application is directed to an absorbent interlabial device. Interlabial devices already belong to the state of the art as indicated on page 1, third paragraph and page 2, first paragraph of the patent application, and as reflected in the pre-characterising portion of claim 1 and acknowledged by the Appellant before the Board. Since document (1), which was considered in the decision under appeal as representing the closest prior art, relates to absorbent articles in

general but does not specifically describe interlabial devices, the Board considers in agreement with the Appellant that the interlabial devices in accordance with the prior art cited in the application in suit represent the closest state of the art and, hence, takes them as the starting point for assessing inventive step.

- 3.3 Having regard to this prior art, the Appellant submitted that the technical problem to be solved by the subject-matter of the patent application was to provide an absorbent interlabial device which reduces friction associated with rubbing of the device against the labial wall and sticking to said walls and which has no tendency to dry the wearer's labia. This problem is also defined in the patent application at page 3, third paragraph.
- 3.4 As the solution to this problem the patent application proposes the absorbent interlabial device according to claim 1, which is characterized in that at least a portion of the body-contacting surface of said device comprises an effective amount of a polysiloxane emollient composition, said emollient composition comprising a substantially water free polysiloxane emollient having a plastic or fluid consistency at 20°C.
- 3.5 No experimental data is given in the application or has been provided by the Appellant with regard to the effects that are purported to be achieved by the claimed interlabial devices. In fact the application does not comprise a single example in which the claimed interlabia device has been tested.

Consequently, the alleged advantages of the claimed device over the closest prior art are not adequately supported by experimental data.

In addition the Board cannot follow the allegation of the Appellant that the skilled person expects from its general knowledge that the treatment of the absorbent device with an emollient necessarily and unambiguously results in all the alleged advantages, namely the reduction of friction, sticking and drying out of the labia. In the absence of corroborating evidence substantiating that the technical problem as defined herein above was effectively solved by the claimed devices, the Appellant has merely speculated, which the Board cannot sanction.

3.6 According to the jurisprudence of the Boards of Appeal, alleged but unsupported advantages cannot be taken into consideration for the determination of the problem underlying the claimed invention (see e.g. decision T 20/81, OJ EPO 1982, 217, point 3, last paragraph of the reasons). Since in the present case the alleged advantages, i.e. reduction of friction, sticking and drying out of the labia, lack the required experimental support, the technical problem as defined above (see point 3.3) needs to be redefined in a less ambitious way, that is, to provide alternative interlabial devices to those known from the closest prior art.

3.7 It remains to be decided whether or not the proposed solution to that objective technical problem, namely the absorbent interlabial devices according to claim 1 of the patent application, is obvious in view of the state of the art.

3.7.1 The skilled person looking for an alternative to the absorbent interlabial devices of the prior art would turn its attention to document (1) which belongs to the same technical field as it relates to absorbent articles which absorb body exudates, such as adult incontinence devices and feminine hygiene garments (page 1, lines 11 and 12; page 6, lines 16, 17, 23 and 24; page 7, lines 9 and 10). According to document (1) the top-sheet of such articles, i.e the body contacting surface of the article, can be treated with a lotion coating composition comprising a substantially water free emollient having a plastic or fluid consistency at 20°C, suitable emollients including polysiloxane compounds (page 4, paragraph (i), page 16, line 30 and 31; page 18, lines 13 and 14; claim 1, paragraph (i)).

The Board concludes from the above that document (1) gives a clear incentive on how to solve the technical problem underlying the patent in suit of providing an alternative interlabial device, namely by providing the body contacting surface of said device, with an effective amount of a polysiloxane emollient composition, said emollient composition comprising a substantially water free polysiloxane emollient having a plastic or fluid consistency at 20°C, thereby arriving at the solution proposed by the patent application.

For these reasons, the subject matter of claim 1 of the main request lacks the required inventive step.

3.7.2 The Appellant argued that document (1) concerned only diapers and the problem of the adherence of bowel

movements (BM) to the skin. Thus, the skilled person would not rely on the teaching of that document when trying to solve problems linked to use of interlabial devices which were not worn on the skin but came into contact with the mucous environment of the labia, known to be more sensitive than normal skin. Therefore, applying the teaching of document (1) to interlabial devices could in the view of the Appellant only be the result of an *ex post facto* analysis of the prior art, i.e. with the knowledge of the claimed invention.

Although document (1) relates to the problem of adherence of BM to the skin, it nevertheless gives a broader teaching since it explicitly addresses absorbent articles in general, including more precisely feminine hygiene articles for which obviously the problem of adherence of BM to the skin does not occur. In addition, since in the present case the skilled person is only looking for an alternative to known interlabial devices, he would not refrain from consulting document (1) simply because that document is primarily faced with a different technical problem than that initially mentioned in the application which, however, no longer applies (paragraph 3.6 above). For these reasons, the Board is convinced that applying the teaching of document (1) to known interlabial devices is not the result of an *ex post facto* analysis of the prior art.

- 3.8 Consequently, the main request has to be refused since the subject matter of claim 1 thereof lacks the required inventive step (Article 56 EPC).

First auxiliary request

4. Claim 1 of the first auxiliary request differs from that according to the main request in adding the feature "wherein said absorbent device is sufficiently flushable that it completely clears the bowl under the flushability test at least 70% of the time in two or fewer flushes." This amendment is supported by page 50, lines 8 and 9 of the application as filed which is in keeping with the requirements of Article 123(2) EPC.

5. Remittal

The Board has not, however, taken a decision on the whole matter, since substantial amendments have been made to independent claim 1 according to the first auxiliary request by including a flushability feature which, although mentioned in the description of the application as filed, was only presented in the proceedings before the Board as an essential feature of the invention for which protection was sought. The decision under appeal dealt exclusively with lack of inventive step of claim 1 according to the main request and did not consider claim 1 in the form of the present auxiliary request as such request was never submitted to the first instance. The added feature requiring that the absorbent device should fulfil particular flushability criteria is substantial in the sense that the assessment of inventive step has to be done on a new basis. Thus, claim 1 according to the first auxiliary request gives rise to fresh issues not yet addressed in examination proceedings constituting a "fresh case" (see e.g. decisions T 63/86, OJ EPO 1988, 224; T 47/90, OJ EPO, 1991, 486).

While Article 111(1), second sentence, first alternative, EPC gives the Boards of Appeal the power to decide in ex-parte proceedings on fresh issues where the application has been refused on other issues, proceedings before the Boards of Appeal in ex-parte cases are primarily concerned with examining the contested decision (see decision G 10/93, OJ EPO 1995, 172, points 4 and 5 of the reasons), fresh issues normally being left to the Examining Division to consider after a referral back, so that the Appellant has the opportunity for these to be examined and decided upon without loss of an instance. Under these circumstances the Board considers it appropriate to exercise the power conferred by Article 111(1), second sentence, second alternative, EPC to remit the present fresh case to the Examining Division for further prosecution.

6. The Board considers that the issues below merit consideration when resuming examination proceedings on the basis of claim 1 of the first auxiliary request. The added feature defines the claimed absorbent devices not by structural characteristics but by an effect to be achieved, namely a specific flushability under given operating conditions. Thus, the added feature needs to be examined as to its suitability for clearly defining the subject-matter for which protection is sought as required by Article 84 EPC, second sentence. In addition, the question arises whether or not the freshly defined invention is disclosed in the application as filed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art, as required by Article 83 EPC.

The remittal of the present case to the Examining Division ensures that the Appellant is given the opportunity to present any comment on any possible fresh objection or document which might become relevant as a consequence of that amendment, if he so wishes, in conformity with his right to be heard pursuant to Article 113(1) EPC.

Order

For these reasons it is decided that:

1. Decision under appeal is set aside.
2. The case is remitted to the department of first instance for further prosecution on the basis of claims 1 to 10 of the first auxiliary request filed with the letter dated 5 May 2006.

The Registrar:

The Chairman:

C. Moser

R. Freimuth