

Internal distribution code:

- (A) [] Publication in OJ
(B) [X] To Chairmen and Members
(C) [] To Chairmen
(D) [] No distribution

**Datasheet for the decision
of 15 March 2007**

Case Number: W 0022/06 - 3.2.02

Application Number: PCT/EP 2005/054976

Publication Number:

IPC: A61M 25/00

Language of the proceedings: EN

Title of invention:

Male incontinence product and package therefor

Applicant:

COLOPLAST A/S

Opponent:

-

Headword:

-

Relevant legal provisions:

PCT Art. 17(3)
PCT Rule 40.1, 40.2, 41.1,2
EPC Art. 150(2), 154(3)
EPC R. 105(3)

Keyword:

"Unity of invention (yes)"

Decisions cited:

G 0001/89

Catchword:

-

Case Number: W 0022/06 - 3.2.02

International Application No. PCT/EP 2005/054976

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 15 March 2007

Applicant: COLOPLAST A/S
Holtedam 1
DK-3050 Humlebaek (DK)

Decision under appeal: Protest according to Rule 40.2(c) of the Patent Cooperation Treaty made by the applicants against the invitation (payment of additional fees) of the European Patent Office (International Searching Authority) dated 7 April 2006.

Composition of the Board:

Chairman: T. K. H. Kriner
Members: R. Ries
S. Hoffmann

Summary of Facts and Submissions

I. The applicant filed an international patent application PCT/EP2005/054976 with 27 claims. Independent claims 1 and 23 read as follows:

"1. A combination of a male incontinence product and a package accommodating the incontinence product in a rolled-up configuration thereof, the incontinence product comprising:

- a penile sheath, which during use is unrolled to define a cavity for a length of the user's penis, and which, in the rolled-up configuration of the incontinence product, is rolled up to form a proximal collar portion of the incontinence product; and
- a drainage portion for connecting the cavity of the sheath to a urine-collecting device;

whereby at least one of the penile sheath and the drainage portion is sufficiently flexible to allow collapsing of the incontinence product when in its rolled-up configuration;

the combination further comprising at least one retention element, which retains the rolled-up incontinence product in a collapsed state when the package is closed."

"23. A method for manufacturing a combination of male incontinence product and a package therefor, wherein male incontinence product comprises:

- a penile sheath, which is rolled up to form a proximal collar portion of the incontinence product, and a drainage portion for connecting a cavity of the sheath to a urine-collecting bag, whereby at least one of the penile sheath and the drainage portion is

sufficiently flexible to allow collapsing of the incontinence product when in its rolled-up configuration;

the method comprising the steps of:

- providing the package in an open state thereof;
- placing the incontinence product in the package;
- collapsing the incontinence product; and
- closing the package in such a way that the incontinence product is retained in its collapsed state in the closed package."

Dependent claims 2 to 22 and 24 to 27 relate to preferred embodiments of the product or the method set out in claim 1 or claim 23, respectively.

II. On 7 April 2006, the EPO acting as an International Search Authority (ISA) sent to the applicant an invitation to pay three (3) additional search fees pursuant to Article 17(3)(a) and Rule 40.1 PCT.

On the extra sheet enclosed with the invitation to pay additional search fees, the ISA stated that the claimed subject matter lacked novelty in view of document

D1: US-A-3 520 305

which disclosed all the technical features set out in product claim 1 and method claim 23. In consequence thereof, a technical relationship involving one or more of the same corresponding special technical features no longer existed between the subject matter of the following groups of dependent claims: 2-4 and 7, 8; 5-6; 9-21; 22. This finding applied also to the independent method claim 23 and the dependent claims 24-25 and

26-27. As this stage, the ISA identified four (4) groups of inventions:

- G1: claims 1-4, 7, 8, 23
- G2: claims 1, 5, 6, 23,
- G3: claims 1, 9-21, 23-25
- G4: claims 1, 22, 23, 26, 27,

each group relating to a different problem.

In the ISA's view, the different inventions were not linked by a single general inventive concept and hence did not meet the requirements of unity of invention pursuant to Rule 13.1 and 13.2 PCT.

III. On 4 May 2006, the appellant paid three (3) additional search fees under protest pursuant to Rule 40.2(c) PCT. In support of the protest, the appellant submitted the following arguments:

Document D1 disclosed the combination of a male incontinence product (10) comprising a penile sheath (14) and a drainage section (16), and a package accommodating the product in a rolled-up configuration (cf. D1, column 4, lines 3 to 11). However, D1 did not disclose that the combination comprised at least one retention element which retained the rolled-up incontinence product in a collapsed state when the package was closed. Consequently, the combination set out in claim 1 was not anticipated by the disclosure of document D1 and therefore novel.

As to the problem to be solved by the claimed combination, the retention element featuring in the

claim 1 of the application ensured that the incontinence product was retained in its collapsed state and allowed for storage of the product in a collapsed state thus occupying less space than known hitherto. Since the prior art failed to give any indication for providing such a retention element, the subject matter of claim 1 also involved an inventive step.

IV. On 1 September 2006, the internal review panel of the EPO acting as ISA concluded after examination of the protest that the invitation was justified in part. Contrary to its initial assessment, the ISA concurred in its review with the appellant's position that the subject matter of claim 1 was novel over the technical teaching of document D1 which did not disclose a retention element. Regarding the extent to which the invitation was found to be unjustified, two (2) additional search fees paid under protest were refunded.

The ISA, however, also stated that the claimed combination of a male incontinence product and a package accommodating the product set out in claim 1 lacked an inventive step with respect to the disclosure of document D1 taken in combination with that of document

D2: US-A-4 972 850.

Given this situation, unity no longer existed between the following groups of inventions:

group 1: claims 1-19, 22-4, 26, 27 and
group 2: claims 20, 2, 25.

The applicant was invited to pay the protest fee within one month pursuant to Rule 40.2(e) PCT.

- V. On 27 September 2006, the applicant paid the required protest fee.

Reasons for the Decision

1. The appeal is admissible.

2. Procedural matter:

- 2.1 Given that the international application under consideration has an international filing date of 3 October 2005, the protest is subject to the Regulations under the PCT as in force from 1 April 2005. Concerning non-unity findings in the international search, amended Rule 40.1 PCT requires that the *"Invitation to pay additional fees provided for in Article 17(3)(a) shall:*

(i) specify the reasons for which the international application is not considered as complying with the requirement of unity of invention;

(ii) invite the applicant to pay the additional fees within one month from the date of the invitation and indicate the amount of those fees to be paid; and

(iii) invite the applicant to pay, where applicable, the protest fee referred to in Rule 40.2(e) within one month from the date of the invitation, and indicate the amount to be paid".

Pursuant to Rule 40.2(c) PCT, second sentence
"Such protest shall be examined by a review body constituted in the framework of the International Search Authority, which to the extent that it finds the protest justified, shall order the total or partial reimbursement to the applicant of the additional fees."

Therefore, the amendments to Article 17(3) and Rule 40.1,2 PCT have the effect that the former requirement to carry out a review of the justification for the invitation to pay additional search fees under Article 17(3)(a) PCT prior to requiring payment of a protest fee (Rule 40.2(e) PCT) has been deleted, and that the applicant is simultaneously invited to pay the protest fee and the additional search fee within a time limit of one month.

These amendments aim to make the protest procedure before the respective ISA more concise and simple. Accordingly, Article 154(3) and Rule 105(3) EPC have been amended by the EPC 2000 which, however, is not yet in force.

A situation of conflict may arise between the amended Regulations under the PCT and the yet not amended Article 154(3) and Rule 105(3) EPC. Such a particular situation is envisaged in Article 150(2) second sentence EPC, which states:

"in the case of conflict, the provisions of the Cooperation Treaty shall prevail."

It follows from the above that the Regulations under the PCT overrule any non-complying provisions of the EPC or other instructions given by the EPO.

As regards Article 154(3) EPC, the Board does not see any reason why this provision could at present contravene Article 17(3) PCT or Rule 41.1,2 PCT, even if Article 154 EPC will no longer be applicable when EPC 2000 enters into force.

Each Board of Appeal, as an organisational part of the European Patent Office (EPO), constitutes a review body within the framework of the EPO as ISA in compliance with Rule 40.2(c), second sentence PCT, having the competence to decide not only on refunds of additional fees paid after invitation but also on the justification of the impugned invitation to pay these additional fees.

The latter competence was not given to the review body by the formerly valid Rule 40.2(e) PCT and Rule 105(3) EPC. Thus, despite of the use of the identical terms "review" in Rule 105(3) EPC and the now valid Rule 40.2(c) second sentence PCT, according to Article 154(3) EPC, only the Boards of Appeal fulfil the qualification required for the review body in Rule 40.2(c)second sentence PCT.

- 2.2 The Board notes that, irrespective of the amended regulations referred to above in detail, the ISA carried out for the present application a prior "internal review" on a so-called voluntary basis as a service of the EPO (see OJ EPO, 3/2005, 226). In doing so, the applicant had not been invited to pay the protest fee in the invitation to pay additional fees (PCT Article 17(3)(a) and Rule 41.1) as required in Rule 40.1(iii), but was invited to pay by the

communication dated 1 September 2006 of the "internal review body".

The legal question of whether or not Rule 105(3) EPC is still applicable either directly or by means of a voluntary service, or whether it must be interpreted in the light of the amended provisions of the PCT in order to avoid a conflict between the provisions of the EPC and the PCT is not decisive in the present case and is, therefore, not addressed by the Board.

3. Factual matters of the Protest:

3.1 The ISA's non-unity objection was based on the disclosure of document D1 US-A-3 520 305 and thus was made "*a posteriori*". As stated in the decision G 1/89 (OJ EPO, 1991, 155), the ISA is empowered to raise an objection for lack of unity "*a posteriori*", i.e. after having taken the prior art into consideration. Decision G 1/89 makes also clear that an objection of this kind can only be based on a provisional opinion on novelty and inventive step which is in no way binding upon the authorities subsequently responsible for the substantive examination (cf. G 1/89, point 8.1 of the grounds).

3.2 The Board has verified the novelty objection to claims 1 and 23 and finds that the claimed combination of a male incontinence product and package is not anticipated by the disclosure of document D1 and is therefore novel.

Specifically, the male urinary device depicted in D1, Figures 1 and 2 and described in column 3, lines 41 to 50 comprises

- (a) a penile sheath (14) which is unrolled during use to define a cavity and is rolled up to form a proximal collar portion (ring 24) and
- (b) a drainage portion (16) including a bowl and lip portion (18, 20) connecting the cavity to the sheath of the urine collecting device.

As further set out in D1, column 4, lines 6 to 11, the urinary device can form a ring (24) in the rolled-up condition, which is advantageous when device (10) is to be stored or packaged at a minimum space.

In contrast to the claimed combination, document D1 is silent regarding the design of the package itself. More importantly, D1 fails to disclose a retention element provided in the package for retaining the rolled-up incontinence product in a collapsed state when the package is closed, as it is specified in claims 1 and 23 of the present application. The Board therefore concludes that the appellant's assessment in its protest is correct, according to which the subject matter of claim 1 is novel vis-à-vis the technical disclosure of document D1. This finding also applies to independent claim 23 which defines the step of retaining the incontinence product in its collapsed state in the closed package.

As previously noted, the novelty of the claimed subject matter in view of D1 was acknowledged in the ISA's internal review dated 1 September 2006.

3.3 Given that novelty cannot be definitely called into question, an objection of non-unity "*a posteriori*" requires further explanation on the basis of a problem to be defined against the cited prior art and the claimed solution(s) within the framework of an inventive step examination. The problem(s) identified in the ISA's invitation are of no immediate assistance here. However, starting from document D1 as the closest prior art and taking into account the explanations set out on page 2, lines 13 of the application, the problem addressed by the invention appears to reside in proposing a package for a male incontinence product which occupies less space, is as discrete as possible and convenient to use and which can be manufactured at reasonable costs. Given that D1 does not deal with the package, this document could not be helpful in solving these problems. Hence, the subject matter of claim 1 also involves an inventive step.

3.4 Since the reasons given in the ISA's invitation of 7 April 2006 for finding non-unity are thus unconvincing, the appellant's protest was entirely justified. Consequently, one additional search fee and also the protest fee are refunded to the applicant pursuant to Rule 40.2(c) PCT.

4. Although the ISA waived the objection of lack of novelty vis-à-vis the disclosure of document D1 in its review of the protest enclosed with the invitation to pay the protest fee according to Rule 40.2(e) PCT dated 1 September 2006, the claimed combination of a incontinence product and package was - in a second line of argument - held to lack an inventive step on the

basis of document D1 taken in combination with the technical disclosure of document D2.

5. According to Rule 40.2(c) PCT, second sentence, the Board's task is limited to the examination of the protest against the invitation to pay additional search fees. In so doing, the Board must not assess any new reasons brought forward in the ISA's internal review of the justification for the invitation, which is not in line with the provisions of Rule 40.2(c)(d)(e) PCT as in force from 1 April 2005, in particular since any such new reasons were unknown to the applicant and therefore could not have been considered in his protest against the invitation.

6. It should be further noted that under Rule 40.2(c) PCT the Board only had to examine whether, considering the reasons given by the ISA's invitation to pay additional fees and the submissions made in support of the protest, the retention of one additional fee was justified. The Board could not investigate ex officio whether an objection of lack of unity would have been justified for reasons other than those given, e.g. after taking into consideration further documents found during the search. It is therefore possible that the objection of lack of unity could be raised again on different grounds in the event of subsequent proceedings under PCT Chapter II.

Order

For these reasons it is decided that:

Reimbursement of the additional search fee and of the protest fee paid by the applicant is ordered.

The Registrar:

The Chairman:

V. Commare

T. K. H. Kriner