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Datasheet for the decision of 4 October 2011

Case Number: T 1716/08 - 3.2.08

Application Number: 97944751.3

Publication Number: 998247

IPC: A61F 5/443

Language of the proceedings: EN

Title of invention:
An ostomy appliance

Patent Proprietor:
Coloplast A/S

Opponent:
Hollister Incorporated

Headword:
-

Relevant legal provisions:
EPC Art. 123(2)

Relevant legal provisions (EPC 1973):
EPC Art. 54(1)(2), 56, 83, 84

Keyword:
"Sufficiency of disclosure (yes)"
"Allowability of amendments (yes)"
"Novelty (yes)"
"Inventive step - main request - (no)"
"Inventive step - auxiliary request - (yes)"

Decisions cited:
-

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 1716/08 - 3.2.08

D E C I S I O N
of the Technical Board of Appeal 3.2.08
of 4 October 2011

Appellant: (Opponent)
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Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 27 June 2008 rejecting the opposition filed against European patent No. 998247 pursuant to Article 101(2) EPC.

Composition of the Board:

Chairman: T. Kriner
Members: P. Acton
U. Tronser

Summary of Facts and Submissions

I. The appellant (opponent) filed a notice of appeal, received at the EPO on 3 September 2008, against the opposition division's decision posted on 27 June 2008 rejecting the opposition against the European patent EP 0 998 247. The appeal fee was paid simultaneously and the statement of grounds was received on 5 November 2008.

II. The appellant requested that the decision under appeal be set aside and that the European patent be revoked.

The respondent requested that the appeal be dismissed or the patent be maintained on the basis of the following documents:

Claims 1 to 6 according to auxiliary request B submitted with letter dated 2 June 2009, description pages 2 to 15 as submitted during the oral proceedings and figures 1 to 18 as granted.

III. Independent claim 1 as granted reads:

"An ostomy sealing member (5, 105) in the form of a hypo-allergenic adhesive, said sealing member being in the form of a mouldable mass (107) or ring (6) which shows an adhesiveness to adhere to the skin and which is displaceable inwardly by finger pressure to seal around an ostomy and between the ostomy and an ostomy appliance, characterised in that the sealing member is a composition made of two different materials laminated together, a mouldable adhesive layer (6, 21, 27, 107) and a mouldable backing (8, 22, 27, 108, 116) and is in

the form of a ring which has a flange (9, 15) stretching from the outer rim thereof,

wherein the mouldable adhesive shows a sufficient cohesion to be removed in one piece without leaving remaining adhesive on the skin or on the ostomy appliance (feature A)."

The designation "feature A" has been introduced by the board.

Claim 1 according to auxiliary request B reads:

"An ostomy appliance comprising a body side member (1, 101) comprising an adhesive wafer (2, 102) for securing the appliance to the user's skin, said wafer having a hole (3, 103) for receiving a stoma and separately exchangeable receiving member or bag secured to the body side ostomy member for receiving secretions from the ostomy, characterised in that the ostomy appliance further comprising a separate sealing member (5, 28, 105) disposed in the hole of the wafer surrounding the stoma, said sealing member being in the form of a hypo-allergenic adhesive, said sealing member being in the form of a mouldable mass (107) or ring (6) which shows an adhesiveness to adhere to the skin and which is displaceable inwardly by finger pressure to seal around an ostomy and between the ostomy and an ostomy appliance, the sealing member is a composition made of two different materials laminated together, a mouldable adhesive layer (6, 21, 27, 107) and a mouldable backing (8, 22, 27, 108, 116) and is in the form of a ring which has a flange (9, 15) stretching from the outer rim thereof, wherein the mouldable adhesive shows a

sufficient cohesion to be removed in one piece without leaving remaining adhesive on the skin or the ostomy appliance."

IV. The following documents filed within the opposition period were relevant for this decision:

D2: EP-A-0 686 381
D3: GB-A-2 290 974

Moreover, the following documents filed during the appeal proceedings played a role:

D14: US-A-5 492 943
D15: EP-A-0 591 898
D16: US-A-4 419 100
D18: US-A-4 650 817
D19: US-A-4 831 070
D20: US-A-4 871 812
D23: "The Shell Bitumen Industrial Handbook", ISBN-O-95 16625-1-1, page 164
D24: WO 98/48858

V. The appellant's arguments can be summarised as follows:

(a) Admissibility of the late filed documents

D14 to D16 and D18 to D20 were filed together with the notice of appeal and therefore at the earliest moment in the appeal proceeding. Moreover, they have been filed as a reaction to the discussion about the composition of the adhesive paste which took place during the opposition proceedings. D14 was particularly relevant since it disclosed a chemical composition

corresponding to the ones disclosed in the patent in suit and hence fell under the wording of claim 1. D23 and D24 were filed later during the appeal procedure in order to provide additional information about the composition of skin friendly adhesives and to prove the change of the commercial name of some copolymers of the family of Kraton®. Therefore, Documents D14 to D16, D18 to D20, D23 and D24 should be admitted into the proceedings.

(b) Main request

Allowability of the amendments

The feature introduced into claim 1 according to which the adhesive is of the hypo-allergenic type had been extracted and isolated from the features of the sealing member according to the embodiment disclosed on page 11. Since all the features of the sealing member described in this embodiment were functionally and structurally linked together, the extraction of a single feature corresponded to an intermediate generalisation and contravened the requirements of Article 123(2) EPC.

Moreover, the features of claim 3 as granted were not disclosed in combination in claims 3 and 7 as originally filed from which they were derived.

Sufficiency of disclosure

The invention was not disclosed in a manner sufficiently clear and complete for it to be carried out by a skilled person.

No test was described to assess whether or not an adhesive showed a "sufficient cohesion to be removed in one piece without leaving remaining adhesive on the skin" (feature A).

Moreover, the patent did not specify that any of the adhesives described in the examples complied with the requirements of feature A. The patent merely specified that the adhesives according to the examples 14 to 19 did not fulfil the requirements of claim 1, since they were made of water dispersible polymers. Therefore, the skilled person would not be able to reproduce the invention without an inventive effort.

Furthermore, claim 1 required that both the backing member and the adhesive mass were hypo-allergenic adhesives. Since the only example of a backing layer was Parafilm® (see [0034]), which was not an adhesive, the patent failed to describe any hypo-allergenic, adhesive backing member.

Novelty

Both D2 and D14 disclosed an ostomy sealing member with all the features of claim 1 as granted. Particularly, both documents disclosed a mouldable adhesive layer with a composition similar to the one disclosed in the preferred embodiments of the patent in suit. Therefore, the adhesives disclosed in D2 and D14 inherently exhibited the characteristic of a sufficient cohesion for it to be removed in one piece without leaving remaining adhesive on the skin or the ostomy appliance.

Moreover, both documents disclosed a flange stretching from the outer rim of the laminated adhesive and backing layer. This feature was shown in the figures of D2 and was disclosed in D14 on column 3, lines 46 to 51 in combination with the reference to the floating flange of D16 (see column 5, line 27).

Inventive step

The most relevant state of the art was the ostomy sealing member according to D2.

Starting from this sealing member, the object to be achieved by the present invention could be seen in the provision of an adhesive which required less cleaning after removal of the seal.

The skilled person would consider the teaching of D14 since it belonged to the same technical area. This document addressed the problem underlying the patent in suit (see column 3, lines 20 to 23) and solved it by providing a sealing member made of an adhesive which remained intact when removed.

Therefore, the skilled person combining the teaching of D14 and D2 would arrive at the subject matter of claim 1 as granted without the need of any inventive activity.

(c) Auxiliary request

Allowability of the amendments and sufficiency of disclosure

The same arguments set out for the main request applied to the auxiliary request.

Inventive Step - Auxiliary request

Since the sealing ring according to D3 was made of a material different from those of the wafer 18 and of the ring 12, it was suitable to be removed as a separate entity and hence has to be considered a "separated sealing member". Therefore, the ostomy appliance according to D3 represented the closest prior art.

Starting from this device, the problem solved by the subject matter of claim 1 was to provide a sealing member which required less cleaning after removal of the seal.

Since D14 addressed the issue of providing a sealing member which could be removed intact, and hence avoiding a subsequent cleaning, it would be obvious for the skilled person to combine the teaching of the two documents, thereby arriving at the content of claim 1 without the need of any inventive activity.

Moreover, the combination of the teaching of D2 and D14 led in an obvious way to the subject matter of claim 1 as well.

Therefore, the subject matter of claim 1 according to auxiliary request B did not involve an inventive step.

VI. The respondent's arguments can be summarised as follows:

(a) Admissibility of the late filed documents

D14 to D16, D18 to D20, D23 and D24 were late filed. Since they were not prima facie relevant for the assessment of the patentability of the patent in suit, they should not be admitted into the proceedings.

In case the Board decided to admit any of these documents into the proceedings, the respondent requested that the case be remitted to the first instance for further prosecution, in order to give the patent proprietor the right of being heard by two instances.

(b) Main request

Allowability of the amendments

The feature of claim 1 according to which the adhesive shall be hypo-allergenic was not functionally and structurally linked to the remaining features of the embodiment disclosed on page 11 and could be extracted in isolation without contravening the requirements of Article 123(2) EPC.

Claim 3 as granted found support in claim 3 and on page 9, line 22 as originally field.

Sufficiency of disclosure

It was clear from the whole of the patent that feature A described an adhesive which could be removed without leaving behind any macroscopic residuals. Therefore, it was not necessary to describe a test for assessing whether or not an adhesive showed a "sufficient cohesion to be removed in one piece without leaving remaining adhesive on the skin", in order to assure a sufficient disclosure of the invention.

Furthermore, since the adhesives described in examples 1 to 13 fulfilled the requirements of claim 1, more than one way of carrying out the invention was disclosed.

Parafilm®, which was disclosed as one suitable material of the backing layer, was indeed not an adhesive. However, the skilled person could find a backing material which fulfilled the requirements of claim 1 without any undue burden.

Novelty

Neither D2 nor D14 disclosed an adhesive which was suitable to be removed in one piece, since both documents used adhesives with compositions corresponding to those of examples 14 to 19 of the patent in suit, which described adhesives that cannot be removed in one piece.

Moreover neither D2 nor D14 disclosed a mouldable backing layer. The adjective "mouldable" implied the capability of a material to take the shape of a mould,

i.e. a plastic deformation and a permanent change in shape. This interpretation was supported by the fact that the gist of the invention was the provision of a backing which protects the mouldable adhesive from the secretions of the stoma. However, this protection was only attainable if the backing was able to deform together with the mouldable adhesive (see page 5, lines 24, 25). The materials used for the backings in D2 and D14, however, were flexible but not mouldable since they could not be deformed plastically during the squeezing out of the mouldable adhesive.

Finally, D14 did not disclose a flange. The reference to the floating flange of D16 was of a general nature and did not explain how the flange should be made. The passage in column 3, lines 46 to 51 did not disclose a flange either, since it merely described the presence of a backing layer along one of the wafer's faces.

Inventive step

Since D14 did not address the problem of reducing the need for cleaning of the sealing member, the skilled person would not have taken this document into consideration. Moreover, even if he did, he would use the adhesive disclosed in the examples of this document. However. since these adhesives were not able to be removed in one piece, even by applying the teaching of D14 to the sealing ring of D2 he would not arrive at the subject matter of claim 1 as granted.

Hence the subject matter of claim 1 involved an inventive step.

(c) Auxiliary request

Allowability of the amendments and sufficiency of disclosure

The submissions put forward with respect to the main request also applied to the auxiliary request.

Inventive Step

Neither D2 nor D3 disclosed the feature according to which the sealing member was separate since this feature had to be interpreted in the sense that the sealing ring was not permanently joined to the further parts of the ostomy appliance.

Since none of the documents used in the procedure disclosed a separate sealing member, there was no suggestion for the use of such an element. Consequently, the subject matter of claim 1 could not be found in an obvious way.

Reasons for the Decision

1. The appeal is admissible.

2. Admissibility of late filed documents

D14 to D16, D18 to D20, D23 and D24 have been filed after the opposition period and are therefore late filed documents. However, since their content is *prima facie* highly relevant for the assessment of the

patentability of both present requests, they are admitted into the proceedings.

When exercising its discretion under Article 111(1) EPC (1973), the Board has to take into consideration the procedural efficiency and the public interests. In the present case a remittal to the first instance only for considering documents which had been filed together with the grounds of appeal and which easily could have been considered by the respondent within the appeal procedure, does not appear to be justified. Therefore and in order to ensure a streamlined and efficient procedure, the case is not remitted to the first instance for further prosecution.

3. Main request

3.1 Allowability of the amendments

In the absence of any clearly recognisable functional or structural relationship among the features of an embodiment, it is allowable to extract an isolated feature from a set of features originally disclosed in combination.

The feature of claim 1 according to which the adhesive is hypo-allergenic is not linked either structurally or functionally to the features according to which the ring has a centrally located hole and a flange made of a mouldable backing. While the latter features refer to the geometry of the ostomy sealing member, the hypo-allergenic nature of the adhesive can be applied to any geometry and hence is independent therefrom.

Moreover, the feature according to which the adhesive is hypo-allergenic is not inextricably linked to the further features of the adhesive disclosed on page 11, lines 13 and 14, namely that it should be soft, easily deformable and non-memory putty. Therefore, these features can be omitted without resulting in an intermediate generalisation.

Finally, the subject matter of claim 3 as granted is disclosed in the application as filed. The feature according to which the sealing member is made of a mouldable sealing ring with a weak elasticity is described on page 9, lines 20 to 22 of the originally filed application.

Therefore, the subject matter of claims 1 and 3 as granted does not extend beyond the content of the application as originally filed.

3.2 Sufficiency of disclosure

From the whole of the disclosure of the patent in suit it is evident that feature A has to be understood in the sense that no macroscopic pieces of the adhesive are left on the skin after the sealing ring is removed and that no solvent is necessary to clean the skin before a new sealing ring is attached to it. Therefore, the skilled person can assess whether an adhesive fulfils the requirements of feature A without the need of any specific test.

Examples 1 to 13 describe adhesives which can be removed without leaving adhesive on the skin and hence fulfil the requirements of feature A. Therefore, the

patent discloses not only one but even several ways of carrying out the invention. The remaining examples 14 to 19 indeed describe water dispersible adhesives which cannot be removed in one piece. This might lead to an inconsistency between the claim and the description, contrary to the requirements of Article 84 EPC (1973), but not to a lack of sufficiency of disclosure.

In the patent the only disclosure of the material of a backing layer is Parafilm®. It is undisputed that this material is not an adhesive and that a sealing member comprising a backing layer made of Parafilm® does not correspond to the claimed invention. However, the skilled person can supplement the information contained in the patent by using his common general knowledge and find an adhesive backing layer suitable to be used in the claimed invention without any undue burden.

Therefore, the claimed invention is sufficiently disclosed to be carried out by the skilled person.

3.3 Novelty - Main request

3.3.1 D2 undisputedly discloses (see particularly Figures 3 and 4):

An ostomy sealing member (12) in the form of a hypo-allergenic adhesive, said sealing member being in the form of a mouldable mass (31) which shows an adhesiveness to adhere to the skin and which is displaceable inwardly by finger pressure to seal around an ostomy and between the ostomy and an ostomy appliance, wherein the sealing member is a composition made of two different materials laminated together, a

mouldable adhesive layer (31) and a backing (25, 29) and is in the form of a ring which has a flange (27) stretching from the outer rim thereof.

Moreover, contrary to the respondent's submissions, D2 further discloses a mouldable backing. The adjective "mouldable" does indeed express that the backing can be shaped in a required shape or form, as can be done by the backing according to D2. However, it does not implicitly require the backing to be plastically deformable and to maintain the new shape permanently as claimed by the respondent.

The respondent argued that this interpretation of the adjective "mouldable" was supported by the fact that the gist of the invention lies in a backing layer which protects the mouldable adhesive in any of its shapes and had to be plastically deformable in order to achieve this protection. It is correct that page 5, lines 24 to 25 describe a specific embodiment with a backing layer sprayed on the mouldable adhesive thereby protecting it from the secretions of the stoma. However, this feature does not imply that the backing layer has to be plastically deformable since the backing layer can protect the adhesive, moulded in different shapes even if it does not extend plastically and does not maintain its new shape permanently.

However, D2 does not disclose an adhesive showing a sufficient cohesion to be removed in one piece without leaving remaining adhesive on the skin or the ostomy device (feature A). This feature is neither an explicit nor an intrinsic characteristic of the adhesives described in the embodiments of D2. It is true that

this document discloses mouldable adhesives with compositions similar to those of the patent in suit. However, these compositions correspond to those examples which do not fall under the scope of claim 1 as granted (examples 14 to 19).

3.3.2 D14 discloses:

An ostomy sealing member in the form of a hypo-allergenic adhesive, said sealing member being in the form of a mouldable mass which shows an adhesiveness to adhere to the skin and which is displaceable inwardly by finger pressure to seal around an ostomy and between the ostomy and an ostomy appliance, wherein the sealing member is a composition made of two different materials laminated together, a mouldable adhesive layer and a mouldable backing, wherein the mouldable adhesive shows a sufficient cohesion to be removed in one piece without leaving remaining adhesive on the skin or on the ostomy appliance (see column 3, lines 20 to 23).

However, D14 does not disclose a sealing member in the form of a ring which has a flange stretching from the outer rim thereof. D14 does indeed refer to a floating flange construction according to D16 (see column 5, lines 28, 29). However, this reference is of a generic nature and does not specify how the flange is supposed to interact with the sealing member. The passage cited by the appellant on column 3, lines 46 to 51 does not disclose the presence of a flange either since it only requires that the backing layer is secured to the pouch without specifying how, and is silent about the presence of a flange.

3.3.3 Therefore, the subject matter of claim 1 as granted is novel with respect to both D2 and D14.

3.4 Inventive step - Main request

3.4.1 Starting from the ostomy sealing member according to D2, which undisputedly represents the closest prior art, the object to be achieved by the present invention lies in the provision of an adhesive which requires less cleaning after removal of the seal.

3.4.2 In order to solve this problem, the skilled person would take D14 into consideration since it belongs to the same technical area and explicitly addresses the problem of an easy removal of the seal (see column 3, lines 20 to 23).

Moreover, when combining the two documents, the skilled person would obviously select only those adhesives of D14 which solve the problem posed and not those which, being water soluble, can only be removed with the additional help of water.

3.4.3 Therefore, by applying the teaching of D14 to the ostomy sealing member according to D2, the skilled person arrives at the subject matter of claim 1 in an obvious way.

Hence the subject matter of claim 1 as granted does not involve an inventive step.

4. Auxiliary request

4.1 Allowability of the amendments and sufficiency of disclosure

Since the arguments brought forward relating to the allowability of the amendments and the sufficiency of disclosure pertain to features which were already present in claim 1 as granted, the same conclusions set out under points 2.1 and 2.2 above apply for the auxiliary request B as well.

4.2 Inventive step

The wording "separate sealing member" can only be understood as referring to a sealing member which can be divided from the remaining parts of the ostomy device so as to represent a separate entity. It furthermore implies that the sealing member can be replaced independently from the ostomy bag and from the body side member.

The sealing member disclosed in D3 is made indeed of a material different from those of the remaining parts of the ostomy appliance. However, this does not imply automatically that it can be considered to be a "separate sealing member". The whole of D3 describes the sealing member as an integral part of the body side member and does not suggest, let alone disclose that the sealing ring might be separated from it. Therefore, D3 does not disclose a separate sealing member.

In D2 the annular film (25) surrounding one side of the sealing member is heat sealed or permanently secured to

the microporous layer of the patch (see page 3, lines 42 to 43). Therefore, D2 does not disclose a separate sealing layer either.

Since neither D3 nor D2 nor any other of the documents on file disclose or suggest a separate sealing member, it is not obvious for the skilled person to modify any of the known ostomy devices in such a way as to provide it with a separate sealing member.

Hence the subject matter of claim 1 according to auxiliary request B involves an inventive step.

Order

For these reasons it is decided that:

The decision under appeal is set aside.

The case is remitted to the Opposition Division with the order to maintain the patent on the basis of the claims 1 to 6 according to auxiliary request B submitted with letter dated 2 June 2009, description pages 2 to 15 as submitted during oral proceedings and figures 1 to 18 as granted.

The Registrar: The Chairman:

V. Commare T. Kriner