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**Datasheet for the decision
of 20 July 2018**

Case Number: T 0161/16 - 3.2.08

Application Number: 06004694.3

Publication Number: 1666008

IPC: A61F5/443, A61F5/448

Language of the proceedings: EN

Title of invention:

Ostomy appliance

Patent Proprietor:

ConvaTec Technologies Inc.

Opponent:

Coloplast A/S

Headword:

Relevant legal provisions:

EPC Art. 100(b), 100(a), 56

Keyword:

Sufficiency of disclosure
Inventive step

Decisions cited:

G 0001/03, T 2005/08

Catchword:



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Case Number: T 0161/16 - 3.2.08

D E C I S I O N
of Technical Board of Appeal 3.2.08
of 20 July 2018

Appellant: Coloplast A/S
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Respondent: ConvaTec Technologies Inc.
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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted on 4 November 2015 rejecting the opposition filed against European patent No. 1666008 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairwoman P. Acton
Members: M. Alvazzi Delfrate
P. Schmitz

Summary of Facts and Submissions

- I. By its decision posted on 4 November 2015 the opposition division rejected the opposition against European patent No. 1 666 008.
- II. The appellant (opponent) lodged an appeal against this decision in the prescribed form and within the prescribed time limits.
- III. The appellant requested that the decision under appeal be set aside and that the patent be revoked. No request for oral proceedings was filed.

The respondent (patent proprietor) requested that the appeal be dismissed and that the patent be maintained as granted or on the basis of auxiliary request 1 filed with letter of 9 August 2016. Oral proceedings were requested as an auxiliary measure.

- IV. Claim 1 of the main request reads as follows (feature references from a) to o) added by the Board):

"a): An ostomy body fitment for attaching an ostomy appliance to a person's body, the body fitment comprising:

b): a pliable adhesive pad (44),

c): the adhesive pad (44) having a first adhesive surface for securing to an individual's skin,

d): and a second adhesive surface opposite to the first adhesive surface; and

e): a shape defining member (46) on one side of the adhesive pad,

f): the shape defining member comprising a first aperture (54) over which the adhesive pad at least partly extends;

g): wherein the pad and the shape defining member together define:

h): a first zone (60) in which the adhesive pad is unsupported by the shape defining member; and

i): a second fixed-shape zone (58) in which the adhesive pad is supported by, and has a shape defined by, the shape defining member;

j): wherein the portions of the pad (44) in the first and second zones are integral with each other,

k): and the first zone (60) extends radially inside the second zone (58) and surrounds a second aperture (52) in the wafer; and

l): the first zone (60) is a re-shapeable zone in which the adhesive pad (44) is plially reshapeable to permit the second aperture (52) to be shaped manually to define a customized aperture for fitting an individual's stoma;

characterized in that:

m): the shape defining member has a contour to impart a shape to the pad to cause the pad to bulge away from said one side on which the shape defining member is located;

n): a linear dimension of the second aperture (52) is less than two thirds of a corresponding linear dimension of the first aperture (54); and

o): wherein the second adhesive surface is substantially exposed in the first zone (60) at least in use to enable the aperture to be enlarged by rolling or folding back a rim portion of the skin adhesive surrounding the aperture into adhesive contact with a portion of the exposed second adhesive surface."

The auxiliary requests have no bearing on the present decision.

V. The following documents played a role for the present decision:

CP3: US -A- 5,618,276;
CP4: US -B- 6,332,879;
CP5: WO -A- 95/24169;
CP6: EP -A- 0 415 282; and
CP10: GB -A- 2 290 974.

VI. The arguments of the appellant can be summarised as follows:

Sufficiency of disclosure

According to the established jurisprudence (G 1/03), if the effect of a patent is expressed in the claim, then this should be objected to under lack of sufficiency if there is lack of reproducibility.

Claim 1 of the patent included the effect "to enable the aperture to be enlarged by rolling or folding back

a rim portion of the skin adhesive surrounding the aperture into adhesive contact with a portion of the exposed second adhesive surface".

The opposition division erred in deciding that this was a simple matter of trial and error for the skilled person. This was because the above effect was not achievable for the preferred embodiments of the invention, mentioned in paragraphs [0034] and [0040]. According to paragraph [0034] the width of the adhesive from an edge of the member aperture to an edge of the pad aperture, i.e. the part that could roll or fold, was at least 3 mm. The thickness was mentioned in [0040], according to which the adhesive preferably consisted of two layers, wherein one layer was 1.27 mm and the other layer was 0.5 mm. This meant that the preferred thickness in total was 1.77 mm. Rolling or folding a free edge with a width of 3 mm and a thickness of close to 2 mm into contact with itself was simply impossible.

Thus, since the effect expressed in the claim could not be reproduced, the invention was not sufficiently disclosed.

Inventive step

The subject-matter of claim 1 did not involve an inventive step in respect of CP3 in combination with CP4, CP4 in combination with CP3, CP10 in combination with CP3, or in view of a partial problems approach.

(a) Starting from CP3 in view of CP4

Similar to the opposed patent, CP3 related to an ostomy appliance designed to provide a secure fit between the

ostomy appliance and the stoma and to decrease skin irritation and patient discomfort. The differences between CP3 and claim 1 were, firstly, that a linear dimension of the second aperture was less than two thirds of the corresponding dimension of the first aperture (feature n)) and, secondly, that the second adhesive surface was substantially exposed in the first zone to enable enlargement of the first aperture by rolling or folding (feature o)) so that it was possible to customise the aperture (feature l)).

The problem facing the skilled person starting from CP3 was to provide an ostomy body fitment allowing for customisation of the aperture to better fit the stoma.

Faced with this problem, the skilled person would quite naturally turn to CP4, which was within the same field of adhesive wafers for ostomy appliances and which specifically dealt with different ways of enlarging the second aperture.

Looking at CP4, the skilled person would realise without undue burden that the embodiment of Figures 8 and 9 presented a solution to the objective technical problem, this solution exactly matching the subject-matter of claim 1.

Firstly, Figures 8 and 9 disclosed a "substantially exposed first zone of adhesive" since the backing was clearly optional. Secondly, the claimed linear dimensions of the apertures were disclosed in Figures 8 and 9 because the central hole in Figure 8, corresponding to the "second aperture" of claim 1, clearly had a diameter less than half the total diameter of the hole and the exposed adhesive surfaces, corresponding to the recited "first aperture". Thirdly

and finally, the embodiment of Figures 8 and 9 clearly allowed for rolling or folding of the exposed adhesive surface, thereby meeting the functional claim limitation, "enable the first aperture to be enlarged by rolling or folding", as recited in claim 1.

Indeed, the "rolling or folding" in claim 1 was not a structural but a functional feature. It was therefore not necessary for the prior art to actually disclose rolling or folding but it sufficed to disclose a structure enabling the rolling or folding function. It was correct that said embodiment of CP4 described an enlargement of the hole by means other than rolling and folding, such as compression. However, the structure of Figures 8 and 9 very clearly also allowed for enlargement by rolling or folding, thus satisfying the claimed functional feature.

Therefore, the subject-matter of claim 1 did not involve an inventive step.

(b) Starting from CP4 in view of CP3

Document CP4 had also been part of opposition proceedings concerning the parent application. In its interlocutory decision dated 29 July 2008, the opposition division in the parent case found that document CP4, then identified as document D2, disclosed in Figures 8 and 9 an embodiment wherein the pad could be rolled or folded back. The opposition division's decision concerning the parent application was subject to appeal and in the relevant decision (T 2005/08), the Board of Appeal did not provide a different opinion on the opposition division's interpretation of the embodiments relating to Figures 8 and 9 of CP4.

Moreover, document CP4 disclosed a second adhesive surface substantially exposed in a first zone and certainly did not teach away from a substantially exposed surface. The sole distinguishing feature over CP4 was thus feature m).

The objective technical problem solved by this feature was how to make an adaptable ostomy fitment suitable also for recessed stomas.

A skilled person faced with the objective technical problem would naturally look to CP3 and would apply the convex shape-defining member in CP3 to arrive at the alleged invention according to claim 1. Additionally, feature m) was also known from CP5 or CP6.

Consequently, granted claim 1 lacked an inventive step over a combination of CP4 and CP3.

(c) Based on a partial problems approach

Features n) and o) made sure that the unsupported region of adhesive provided enough adhesive material to enable the function of rolling back the rim into adhesive contact with its own adhesive surface. The effect of the convex shape-defining member in feature m), i.e. making the stoma better protrude from the skin, was completely unrelated to making the fitment rollable. Hence, they solved different partial problems. The first partial problem was how to make a recessed stoma protrude from the skin. This was solved by the shape-defining member in feature m). The second problem was how to make the stoma-receiving aperture adaptable to suit individual stomas. This was solved by the nature of the first zone defined in features n) and o). It had already been shown above that feature m)

was disclosed in CP3 and that features n) and o) were disclosed in CP4.

Thus, based on this partial problems approach, it was concluded that claim 1 lacked an inventive step because the characterising features were not functionally interdependent and were each individually known from the prior art for providing the exact same effects as in the patent.

(d) Starting from CP10 in view of CP3

CP10, which was the document described in the background sections [0002]-[0003] of the patent and which should be admitted into the procedure, disclosed all the features of claim 1 except for features j) and m).

The objective technical problem solved by those distinguishing features could be formulated as how to provide a simpler adaptable ostomy fitment for recessed stomas.

Faced with this objective problem, the skilled person would have no problem in identifying CP3 as concerning the same technical area and providing exactly the solution expressed by features j) and m).

Consequently, granted independent claim 1 lacked an inventive step over the combination of CP10 and CP3.

VII. The arguments of the respondent can be summarised as follows:

Sufficiency of disclosure

Reshaping of the rim to enlarge the aperture was permitted by the adhesive contact. Moreover, the patent did not disclose that an adhesive with a width of 3 mm must have a thickness of 1.77 mm. The appellant had not provided any proof of the alleged insufficient disclosure. The person skilled in the art would be able to carry out the invention on the basis of the whole disclosure of the patent and his common general knowledge.

Inventive step

The claimed subject-matter involved an inventive step because it was not rendered obvious by the prior art.

(a) Starting from CP3 in view of CP4.

Starting from CP3 the problem to be solved was the provision of an ostomy fitment with a convex pressure ring that could maintain a moulded custom shape around the stoma. CP4 did not relate to this problem and would thus not be consulted by the person skilled in the art. Moreover, in CP4 the adhesive seal was intended to resume its original shape and did not exhibit feature o). Hence, CP4 taught away from the claimed invention.

(b) Starting from CP4 in view of CP3.

The decisions of the opposition division and the Board of Appeal concerning the parent application had no implications for the present case.

As already explained, the claimed fitment was distinguished from CP4 not only by feature m) but also by feature o). Thus, CP4 was not the closest prior art.

It was not obvious to arrive at the combination of features m) and o), the latter of which was not disclosed or suggested by either CP4 or CP3.

(c) Based on a partial problems approach.

Features m), n) and o) all addressed the problem of the distorting force applied to the formable adhesive mass in a convex ring. Thus, they interacted and it was not correct to formulate two partial problems. Furthermore, the choice of a "planar" type fitment as closest prior art was artificial, because convex-type fitments such as the claimed one and planar fitments were two different technical areas.

(d) Starting from CP10 in view of CP3.

CP10, which was only filed with the grounds of appeal, should not be introduced into the proceedings because it was late-filed and not *prima facie* relevant.

In any event CP3 did not provide a motivation to modify CP10 in the claimed sense.

Reasons for the Decision

1. Right to be heard

The appellant has not filed a request for oral proceedings. Since the grounds on which this decision is based were known to the appellant, either from the appealed decision or from the respondent's submissions, the appellant's right to be heard (Article 113(1) EPC) is met and the Board could give this decision without the need for oral proceedings.

2. Sufficiency of disclosure

According to claim 1 the second adhesive surface is substantially exposed in the first zone at least in use to enable the aperture to be enlarged by rolling or folding back a rim portion of the skin adhesive surrounding the aperture into adhesive contact with a portion of the exposed second adhesive surface.

The appellant refers to paragraphs [0034] and [0040] and argues that it was not possible to roll or fold a free edge with a width of 3 mm and a thickness of close to 2 mm into contact with itself. Thus, since the effect expressed in the claim could not be reproduced for the preferred embodiments of the invention, the invention was not sufficiently disclosed.

However, the patent in suit does not disclose as a preferred embodiment an adhesive layer with a width of 3 mm and a thickness of close to 2 mm. Rather, paragraph [0040] states that the first adhesive layer 62 may have a thickness between about 1 mm and 1.5 mm, typically about 1.27 mm, whereas the second adhesive layer may have a thickness between about 0.2 mm and 1 mm, typically about 0.5 mm. Paragraph [0034] discloses a width of the adhesive from an edge of the member aperture to a closest edge of the pad aperture of at least 3 mm, more preferably at least 5 mm, more preferably at least 7 mm. Thus, the typical dimensions are rather a width of at least 7 mm and a thickness of 1.77 mm.

Moreover, as already pointed out by the opposition division (appealed decision, page 4, last paragraph), the appellant, who has the burden of proof, failed to

show that the person skilled in the art would not be able to select an appropriate adhesive material and an appropriate geometry to realise the rolling or folding back.

Therefore, the claimed invention is sufficiently disclosed.

3. Main request - inventive step

3.1 Starting from CP3 in combination with CP4

3.1.1 CP3 which, like the patent in suit, relates to an ostomy appliance for recessed stomas (due to the bulging shape), represents the closest prior art. It discloses an ostomy body fitment for attaching an ostomy appliance to a person's body, the body fitment comprising: a pliable adhesive pad (11), the adhesive pad having a first adhesive surface for securing to an individual's skin, and a second adhesive surface opposite to the first adhesive surface and a shape-defining member (12) on one side of the adhesive pad. The shape-defining member comprises a first aperture (28) over which the adhesive pad at least partly extends. The pad and the shape-defining member together define: a first zone in which the adhesive pad is unsupported by the shape-defining member; and a second fixed-shape zone in which the adhesive pad is supported by, and has a shape defined by, the shape-defining member (column 4, line 66, to column 5, line 2); wherein the portions of the pad in the first and second zones are integral to each other, and the first zone extends radially inside the second zone and surrounds a second aperture in the wafer, and the shape-defining member has a contour to impart a shape to the pad to cause the pad to bulge away from said one side on which

the shape-defining member is located (see Figures 1 and 2).

3.1.2 The subject-matter of claim 1 differs from this fitment in that the first zone is a reshapeable zone in which the adhesive pad is plially reshapeable to permit the second aperture to be shaped manually to define a customised aperture for fitting an individual's stoma; and a linear dimension of the second aperture is less than two thirds of a corresponding linear dimension of the first aperture; and wherein the second adhesive surface is substantially exposed in the first zone at least in use to enable the aperture to be enlarged by rolling or folding back a rim portion of the skin adhesive surrounding the aperture into adhesive contact with a portion of the exposed second adhesive surface (features l), n) and o)).

3.1.3 The Board concurs with the appellant that the problem solved by means of these features is to provide an ostomy body fitment allowing for customisation of the aperture to better fit the stoma (paragraph [0009] of the patent).

3.1.4 In view of this problem the person skilled in the art would have consulted CP4, which deals with the same problem (column 2, lines 56-62). However, CP4 does not hint at the claimed solution.

In Figures 8 and 9, to which the appellant refers, the customisation is realised in a different way than in the device according to claim 1, namely by compressing the grooves 21 (from the position of Figure 8 to the position of Figure 9).

The appellant did not dispute it but argued that the structure shown in Figures 8 and 9 enables the aperture to be enlarged by rolling or folding. However, whether or not this is the case depends on the geometry, in particular the thickness, of the adhesive 7 and its mechanical properties. CP4 does not clearly and unambiguously disclose that this is the case.

The fact that a different view was taken by the opposition division dealing with patent No. EP 1378219 issued from the parent application of the patent in suit is irrelevant since decisions of the opposition divisions are not binding for the boards of appeal. As regards the appeal decision T 2005/08 concerning the patent issued from the parent application, the Board points out that said decision does not deal at all with the disclosure of CP4.

For the sake of completeness it is noted that CP4 discloses other embodiments where the adhesive pad is rolled (see for instance Figures 6 and 7) but in said other embodiments the pad comprises a mouldable backing 19 that covers the adhesive mass so that, contrary to what is required by claim 1, the rim portion of the skin adhesive surrounding the aperture cannot be brought into adhesive contact with a portion of the exposed second adhesive surface.

Indeed, in contrast to the patent, there is no need in CP4 to have a contact between adhesive surfaces because the hole has to be enlarged only temporarily and then reverts to the original form to snugly fit the stoma (column 3, lines 16-27, and column 6, lines 23-29). Hence, CP4 does not point to the claimed solution.

As a consequence, the claimed subject-matter involves an inventive step starting from CP3 in view of CP4.

3.2 Starting from CP4 and combining it with CP3.

The attack starting from CP4 and combining it with CP3 is not convincing either. For the reasons explained above, CP4 does not disclose, contrary to the appellant's opinion, the combination of rolling or folding with an arrangement wherein the adhesive surfaces can be brought into contact with each other (feature o)). Since this feature is not disclosed in CP3 either, the claimed subject-matter involves an inventive step starting from CP4 in view of CP3. The same applies when CP5 or CP6, which likewise don't disclose feature o), are considered instead of CP3.

3.3 In view of a partial problems approach

The attack "based on a partial problems approach" (point 6.3 of the grounds of appeal) is not properly substantiated because the appellant fails to clearly identify the closest prior art. Be that as it may, this attack also rests on the premise that CP4 discloses features (n) and (o), which, as explained above, is not correct. Thus this attack is not convincing either.

3.4 Starting from CP10 in view of CP3

3.4.1 CP10 corresponds to the prior art shown in Figures 1 and 2 of the patent in suit and discussed in the decision under appeal (page 5). Hence, its introduction into the appeal proceedings does not represent a fresh case and there is no reason to disregard it.

3.4.2 CP10 discloses an ostomy body fitment for attaching an ostomy appliance to a person's body, the body fitment comprising: a pliable adhesive pad (18, 24), the adhesive pad having a first adhesive surface for securing to an individual's skin, and a second adhesive surface opposite to the first adhesive surface and a shape-defining member (16) on one side of the adhesive pad. The shape-defining member comprises a first aperture over which the adhesive pad at least partly extends (see Figure 1). The pad and the shape-defining member together define: a first zone in which the adhesive pad is unsupported by the shape-defining member; and a second fixed-shape zone in which the adhesive pad is supported by, and has a shape defined by, the shape-defining member (Figures 1 and 2). The first zone is a re-shapeable zone in which the adhesive pad is plially reshapeable to permit the second aperture to be shaped manually to define a customised aperture for fitting an individual's stoma (page 4, lines 6-8). Figure 1 shows that a linear dimension of the second aperture is less than two thirds of a corresponding linear dimension of the first aperture. The second adhesive surface is substantially exposed in the first zone and it is considered suitable to enable the aperture to be enlarged by rolling or folding back a rim portion of the skin adhesive surrounding the aperture into adhesive contact with a portion of the exposed second adhesive surface.

3.4.3 It is undisputed that CP10 does not disclose that

- the portions of the pad in the first and second zones are integral with each other, and the first zone extends radially inside the second zone and surrounds a second aperture in the wafer (feature j)); and
- the shape-defining member has a contour to impart a shape to the pad to cause the pad to bulge away from

said one side on which the shape defining member is located (feature m)).

The appellant argued that the problem solved starting from CP10 was the provision of a simpler adaptable ostomy fitment for recessed stomas and that CP3 rendered it obvious to solve said problem by features j) and m).

However, starting from CP10, which shows a planar type ostomy fitment, i.e. a fitment not suitable for recessed stomas, for providing an ostomy fitment for recessed stomas, represents an *ex-post facto* analysis. Moreover, even doing so and considering the teaching of CP3, the person skilled in the art would not have isolated features j) and m) but rather taken the solution of CP3 en bloc. This applies in particular to the adhesive pad. There is no reason to realise the adhesive pad of CP10, which exhibits regions with completely different properties (one pressure adhesive wafer and one mouldable putty adhesive) as an integral part. If instead the choice is for the adhesive pad of CP3 (which is integral) the solution proposed by CP3 does not exhibit the combination of rolling and adhesive contact required by the claim.

Therefore, the appellant's argument in view of CP10 and CP3 is not convincing either.

3.5 Therefore, the subject-matter of claim 1 involves an inventive step.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairwoman:



C. Moser

P. Acton

Decision electronically authenticated