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**Datasheet for the decision
of 8 November 2011**

Case Number: T 1650/09 - 3.2.08

Application Number: 95927442.4

Publication Number: 954342

IPC: A61F 5/448

Language of the proceedings: EN

Title of invention:

Ostomy appliance and wound drainage device

Patent Proprietor:

ConvaTec Technologies Inc.

Opponents:

Coloplast A/S
Hollister Incorporated

Headword:

-

Relevant legal provisions:

EPC Art. 100(a), 123(2), 84, 56
RPBA Art. 13(1)

Keyword:

"Late-filed request (admitted)"
"Added subject-matter (no)"
"Clarity (yes)"
"Inventive step (yes)"

Decisions cited:

T 0681/06

Catchword:

-



Case Number: T 1650/09 - 3.2.08

D E C I S I O N
of the Technical Board of Appeal 3.2.08
of 8 November 2011

Appellant I: Coloplast A/S
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Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office posted
4 June 2009 concerning maintenance of European
patent No. 954342 in amended form.

Composition of the Board:

Chairman: T. Kriner
Members: M. Alvazzi Delfrate
E. Dufrasne

Summary of Facts and Submissions

- I. European patent No. 954 342 was opposed on the basis of Article 100(a), 100(b) and 100(c) EPC. With its decision posted on 27 February 2006 the opposition division revoked the patent, on the grounds that all the requests then on file contravened either Article 123(2) or Article 83 EPC.
- II. The patent proprietor filed an appeal against said decision. By its decision of 4 December 2007 (T 681/06, not published in OJ EPO) the competent board of appeal remitted the case to the first instance for prosecution on the basis of the fifth auxiliary request then on file, which was found to comply with the requirements of Articles 123(2), 83 and 84 EPC.
- III. In its decision on the maintenance of the patent in amended form, posted on 4 June 2009, the opposition division found that the said request also met the requirements of Article 100(a) EPC.
- IV. The patent proprietor lodged an appeal against this decision on 10 August 2009, paying the appeal fee on the same day. The statement setting out the grounds of appeal was received on 14 October 2009.

Further appeals were lodged by opponent 1 and opponent 2, on 14 August 2009 and 12 August 2009 respectively, paying the appeal fees at the same time. The statements setting out the grounds of appeal were received on 14 October 2009 (opponent 1) and on 13 October 2009 (opponent 2).

V. Oral proceedings before the board of appeal were held on 8 November 2011.

The appeal of the patent proprietor was withdrawn.

The appellants (opponents) requested that the decision under appeal be set aside and that the patent be revoked.

The respondent (patent proprietor) requested that the decision under appeal be set aside and that the patent be maintained on the basis of the request filed at the oral proceedings.

VI. Claim 1 of this request reads as follows:

"An ostomy appliance or wound drainage device comprising:

(a) a receptacle (8);

(b) a single pair of first and second coupling devices, said first coupling device (4) having a first surface operatively engaged to the receptacle and an opposed surface for releasably engaging the second coupling device to form a releasable fluid tight seal therewith; and

(c) said second coupling device (6) having a first surface for operative contact with a patient's skin (16) and an opposed surface for releasably coupling to the first coupling device, at least one of the respective opposed surfaces of said first (4) and second (6) coupling devices having thereon a single layer of a water-washable adhesive composition which provides releasable and resealable fluid-tight engagement of said first and second coupling devices,

while the second coupling device remains in operative contact with the patient's skin (16), wherein said adhesive composition is water-washable (i) to enable contaminants to be removed from the surface of the adhesive by washing with water and (ii) without retaining cleaning implement fibres on the surface of the adhesive, said adhesive composition is resealable after washing, said adhesive composition is hydrophobic and insoluble in water, and said adhesive composition is an elastomeric composition having a modulus of elasticity of from about 1 to 100 psi and an internal viscosity of from about 1000 to 20,000 poises, whereby the modulus of elasticity is sufficient to enable waste particles to be readily removed therefrom, and the internal viscosity is low enough to enable water-washing and high enough to provide tack; wherein said opposed surface of said first coupling device is comprised of a film or web; said opposed surface of said second coupling device is comprised of a film or web; said first coupling device further comprises a passageway (24) extending through the first coupling device to end flush with said opposed surface of the first coupling device, or to end flush with said single layer of water-washable adhesive if provided on said opposed surface; said second coupling device further comprises a passageway (22) extending through the second coupling device to end flush with said opposed surface of the second coupling device, or to end flush with said layer of water-washable adhesive if provided on said opposed surface; whereby the first and second coupling devices are attachable together by said water washable adhesive,

with said passageways aligned for passing stomal waste escaping from the stoma to the receptacle."

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

D10: US-A-3 682 690 and

D12: US-A-5 429 626.

VIII. The arguments of the appellants can be summarised as follows:

Admissibility of the respondent's request

Since the claims underlying the respondent's request were introduced into the appeal proceedings for the first time with letter dated 7 October 2011, they were late-filed. Moreover, they were prima facie not allowable. Therefore, the respondent's request should not be admitted into the appeal proceedings.

Article 123(2) EPC

The patent application as originally filed did not disclose that the opposed surfaces of the first and second coupling devices, at least one of which had a single layer of a water-washable adhesive composition thereon, were comprised of a film or web.

It was true that claim 16 of the patent application as filed mentioned a film or web. However, that claim, together with claim 14 upon which it depended, merely disclosed that each of the first and second coupling devices comprised a substrate, the adhesive composition

being placed on at least one of said substrates, which substrate was comprised of a film or web. Hence it did not disclose that the adhesive composition was placed on a surface comprised of a film or web.

As to the passages on pages 7 and 13 of the description which also mentioned a film or web, they both related to the embodiment shown in Figure 1, which had adhesive applied to both the opposed surfaces. Since this was not necessarily the case for the appliance according to present claim 1, said passages could not provide a basis for the amendment under consideration either.

Additionally, the application as originally filed did not disclose the features according to which each of the first and second coupling device further comprised a passageway extending through it to end flush with the opposed surface, or to end flush with the single layer of water-washable adhesive if provided on said opposed surface.

It was true that Figures 1, 2a and 2b of the application as filed showed two passageways extending respectively through the first and second coupling devices and ending even with the single layer of water-washable adhesive or, when no adhesive was provided on said opposed surface, with the opposed surface of the coupling device. However, said figures showed also that the passageway extending through the second coupling device ended even with the first surface for operative contact with a patient's skin. Since this feature was not included in present claim 1, the amendment under consideration represented an unallowable intermediate generalisation.

Article 84 EPC

Moreover, it was not clear what was meant by a passageway ending flush with the opposed surface, or with the single layer of water-washable adhesive if provided on said opposed surface. Hence, the amendments under considerations lacked clarity.

Priority

The priority document of the patent in suit did not disclose the ranges of modulus of elasticity and internal viscosity according to present claim 1. Therefore, the priority claim of the patent in suit was invalid and D12 belonged to the prior art to be considered for inventive step.

Inventive step

D12 represented the most relevant prior art and disclosed in the drawings an ostomy appliance comprising:

- (a) a receptacle;
- (b) a single pair of first and second coupling devices, said first coupling device having a first surface operatively engaged to the receptacle and an opposed surface for releasably engaging the second coupling device to form a releasable fluid-tight seal therewith; and
- (c) said second coupling device having a first surface for operative contact with a patient's skin and an opposed surface for releasably coupling to the first coupling device.

Moreover, it disclosed in column 2, lines 18-39 that one of the respective opposed surfaces of said first and second coupling devices had thereon a single layer of an adhesive composition which provided releasable and resealable fluid-tight engagement of said first and second coupling devices, while the second coupling device remained in operative contact with the patient's skin. The first and second coupling devices were attachable together by said water-washable adhesive, with passageways extending through them aligned for passing stomal waste escaping from the stoma to the receptacle.

According to the tests disclosed in D12, said adhesive composition was water-washable to enable contaminants to be removed from the surface of the adhesive by washing with water. Accordingly, the adhesive was an elastomeric composition whose modulus of elasticity was sufficient to enable waste particles to be readily removed therefrom, and whose internal viscosity was low enough to enable water-washing and high enough to provide tack.

Starting from D12 the object underlying the claimed invention could be seen as providing a device which was optimised for cleaning.

This object was achieved with the claimed device

- by the adhesive composition being a hydrophobic elastomeric composition having a modulus of elasticity of from about 1 to 100 psi and an internal viscosity of from about 1000 to 20,000 poises; and

- by the opposed surfaces of the first and second coupling device being comprised of a film or web.

The features according to which each of the first and second coupling device further comprised a passageway extending through it to end flush with said opposed surface of the first coupling device, or to end flush with the single layer of water-washable adhesive if provided on said opposed surface, could not be regarded as distinguishing features, in view of the ambiguous nature of the term "flush", which could encompass the arrangement shown in the drawings of D12. Moreover, even considering that this feature was a distinguishing one, it did not provide any technical contribution to the achievement of the object above.

D10, although not relating to ostomy appliances, disclosed that an adhesive hydrophobic elastomeric composition with a modulus of elasticity of from about 1 to 100 psi and an internal viscosity of from about 1000 to 20,000 poises was easy to clean and to reuse. Hence, it was obvious to choose this adhesive for the appliance of D12 in order to achieve the object above.

Since films and webs were commonly used in the field of ostomy appliances, the choice of these materials for the opposed surfaces in the appliance of D12 was also obvious.

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

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

Admissibility of the respondent's request

The claims of the respondent's request had been filed one month before the oral proceedings. Moreover, they corresponded to those already filed during the opposition proceedings as a second auxiliary request with the letter dated 9 April 2009. Hence, they could not take the appellants by surprise. Therefore, the respondent's request should be admitted into the proceedings.

Article 123(2) EPC

The patent application as originally filed disclosed in claim 16 and in the description that the adhesive composition was directly applied on at least one of the substrates of the first and second coupling devices which comprised a film or web. Hence it disclosed, in accordance with present claim 1, that the adhesive was upon at least one of the opposed surfaces of the first and second coupling devices, which were comprised of a film or web.

The application as originally filed disclosed also the features according to which each of the first and second coupling devices further comprised a passageway extending through it to end flush with the opposed surface, or to end flush with the single layer of water-washable adhesive if provided on said opposed surface. Said features were clearly shown in Figures 1, 2a and 2b, which depicted two passageways extending

through the first and second coupling devices and ending flush with the single layer of water-washable adhesive or, when no adhesive was provided on said opposed surface, with the opposed surface of the coupling device. As to the further feature shown in the drawings according to which the passageway extending through the second coupling device ended even with the first surface for operative contact with a patient's skin, this feature was clearly not correlated with the arrangement of the other end of the passageway. Hence, the amendment under consideration was not an unallowable intermediate generalisation.

Article 84 EPC

As the meaning of the term "flush" was perfectly clear, no lack of clarity was caused by introducing the feature according to which a passageway ended flush with the opposed surface, or with the single layer of water-washable adhesive if provided on said opposed surface.

Inventive step

D12, which belonged to the prior art in view of the invalid priority claim, could be considered as the most relevant prior art.

Starting from this document, the object underlying the claimed invention could be seen as providing a device which was optimised for cleaning.

This object was achieved by the claimed device in that

- the adhesive composition was a hydrophobic elastomeric composition having a modulus of elasticity of from about 1 to 100 psi and an internal viscosity of from about 1000 to 20,000 poises;
- the opposed surfaces of the first and second coupling device were comprised of a film or web; and
- the passageways extending through each of the first and second coupling device ended flush with said opposed surface, or with the single layer of water-washable adhesive if provided on said opposed surface.

D12 did not disclose passageways ending in that way, since it showed a curb at the end of one of the passageways.

The arrangement of the passageways according to present claim 1 contributed to achieving the object above, since the absence of corners and recesses at the end of the passageway rendered the cleaning of the appliance easier.

Since the prior art did not disclose or suggest the feature mentioned above, the subject-matter of claim 1 involved an inventive step.

Reasons for the Decision

1. The appeals of opponents 1 and 2 are admissible.

2. Admissibility of the respondent's request

According to Article 13(1) of the Rules of Procedure of the Boards of Appeal (OJ EPO 11/2011, page 536), any amendment to a party's case after it has filed its grounds of appeal or reply may be admitted and considered at the board's discretion. That discretion is to be exercised in view inter alia of the complexity of the new subject-matter submitted, the state of the proceedings and the need for procedural economy.

In the present case it is true that the claims underlying the respondent's request had been introduced into the appeal proceedings only with letter dated 7 October 2011. However, said claims correspond to those already filed during the opposition proceedings as a second auxiliary request with letter dated 9 April 2009. Hence, they do not raise any matter which could take the appellants or the board by surprise. Moreover, no reason can be seen for considering the request as prima facie not allowable. Under these circumstances the respondent's request is admitted into the proceedings.

3. Article 123(2) EPC

3.1 During the present appeal proceedings claim 1 was amended by introducing the features according to which the opposed surfaces of the first and second coupling devices are comprised of a film or web.

The patent application as originally filed discloses that each of the first and second coupling devices comprises a substrate, the adhesive composition being

placed on at least one of said substrates, which substrate is comprised of a film or web (see claims 14 and 16). In the absence of any indication to the contrary the person skilled in the art understands it to mean that the adhesive is on the film or web, i.e. that it is placed on surfaces comprised of a film or web. This is also in agreement with what is shown in the specific embodiment of Figure 1. Hence, the amendment above is clearly and unambiguously derivable from the application as originally filed.

- 3.2 Present claim 1 was further amended by introducing the features according to which each of the first and second coupling device further comprises a passageway extending through it to end flush with the opposed surface, or to end flush with the single layer of water-washable adhesive if provided on said opposed surface; whereby the first and second coupling devices are attachable together by said water-washable adhesive, with said passageways aligned for passing stomal waste escaping from the stoma to the receptacle.

The patent application as originally filed discloses two passageways (24, 22) extending through the first and second coupling devices and being aligned for passing stomal waste escaping from the stoma to the receptacle (see Figures 1, 2a and 2b, as well as page 13, lines 18-27). Moreover, Figures 1, 2a and 2b of the application as filed clearly show that those passageways end even, i.e. flush, with the single layer of water-washable adhesive or, when no adhesive is provided on said opposed surface, with the opposed surface of the coupling device.

It is true, as submitted by the appellants, that said figures show that the passageway (22) extending through the second coupling device also ends flush with the first surface for operative contact with a patient's skin. However, it is clear that there is no functional link between the arrangement of the passageway at the surface for operative contact with the patient's skin and that at the surface opposed to the other coupling device. As a consequence, said further amendment is not an unallowable intermediate generalisation and does not introduce subject-matter which extends beyond the content of the application as filed.

4. Article 84 EPC

The term "flush" literally means even or level with an adjacent surface. Hence, the wording of present claim 1 taken literally means that the passageways end even with the single layer of water-washable adhesive or with the opposed surface of the coupling device. No ambiguity can be seen in this meaning, which is also in accordance with the arrangement shown in the figures of the patent. Therefore, the amendments under consideration do not lack clarity.

5. Priority

It is undisputed that the priority claim of the patent is invalid for the subject-matter of the present request, since the priority document is silent on the ranges of modulus of elasticity and internal viscosity according to present claim 1. Therefore, D12, published in the priority interval of the patent in suit, belongs to the prior art to be considered for inventive step.

6. Inventive step

6.1 It is common ground that D12, which discloses an appliance having a great number of features in common with the claimed one and also deals with the problem of providing a connection between the pouch and the second coupling device which is releasable, can be water-washed and resealed (see column 5, lines 36 to 39 and column 6, lines 6 to 9), represents the most relevant prior art.

This document undisputedly discloses an ostomy appliance (10) comprising:

- (a) a receptacle (14);
- (b) a single pair of first and second coupling devices, said first coupling device (70, 72) having a first surface operatively engaged to the receptacle and an opposed surface for releasably engaging the second coupling device (40) to form a releasable fluid-tight seal therewith (see column 2, lines 13-18); and
- (c) said second coupling device having a first surface for operative contact with a patient's skin and an opposed surface for releasably coupling to the first coupling device, one of the respective opposed surfaces of said first and second coupling devices (the surface of the first coupling device) having thereon a single layer (72) of an adhesive composition which provides releasable and resealable fluid-tight engagement of said first and second coupling devices (see column 2, lines 18-39), while the second coupling device remains in operative contact with the patient's skin.

Moreover, according to D12 said adhesive composition is elastomeric (see column 2, lines 28-30) and water-washable to enable contaminants to be removed from the surface of the adhesive by washing with water (see column 6, lines 40-55). Accordingly, the adhesive is an elastomeric composition whose modulus of elasticity is sufficient to permit waste particles to be readily removed therefrom, and whose internal viscosity is low enough to enable water-washing and high enough to provide tack. The first and second coupling devices are attachable together by said water-washable adhesive, with two passageways extending through respectively said first and second coupling device being aligned for passing stomal waste escaping from the stoma to the receptacle.

The appellants submitted that the feature according to which each of said passageways extending through the coupling devices ends flush with said opposed surface, or with the single layer of water-washable adhesive if provided on said opposed surface, was also known from D12. However, this argument is not convincing, since the passageway (42) extending through the second coupling device (40) disclosed in D12 exhibits an annular curb (46) at its end corresponding to the surface opposed to the first coupling device (see Figures 2 and 3). Accordingly, said passageway does not end flush with said opposed surface.

- 6.2 Starting from D12, the object underlying the claimed invention can be seen as providing a device which is optimised for cleaning (see paragraphs [0013] and [0014] of the patent in suit).

This object is achieved according to claim 1 in that

- the adhesive composition is a hydrophobic elastomeric composition having a modulus of elasticity of from about 1 to 100 psi and an internal viscosity of from about 1000 to 20,000 poises;
- the opposed surfaces of the first and second coupling device are comprised of a film or web; and
- each of the passageways extending through said coupling devices ends flush with said opposed surface, or with the single layer of water-washable adhesive if provided on said opposed surface.

The selection of a modulus of elasticity and an internal viscosity in accordance with present claim 1 provides an adhesive which, while being easy to be cleaned with conventional cleaning implements, provides sufficient tack (see paragraphs [0028] to [0032]). Moreover, contrary to the appellants' view, the arrangement of the ends of the passageways also contributes to the object above, since the ease of cleaning is further improved by the fact that the passageways in the coupling devices end flush, i.e. without recesses, with the surfaces which have to be cleaned.

- 6.3 The prior art does not render it obvious to achieve the object above by providing the device of D12 with passageways which end in this way.

D12 itself, which presents the annular curb at the end of the passageway as an essential feature of the appliance (see claim 1 and column 2, lines 40 to 49), teaches away from a passageway through the second coupling device ending flush with the surface opposed to the first coupling device or with the adhesive layer.

As to D10, this document cannot render the claimed invention obvious either, since it does not even relate to ostomy appliances, let alone to the problem of cleaning them.

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

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the department of first instance with the order to maintain the patent on the basis of:
 - claims 1 to 14 of the request filed at the oral proceedings;
 - pages 2 to 8 of the amended description filed at the oral proceedings; and
 - Figures 1 to 2B of the patent as granted.

The Registrar:

The Chairman:

V. Commare

T. Kriner