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**Datasheet for the decision of 2 September 2025**

**Case Number:** T 0974/23 - 3.2.02

**Application Number:** 11823854.2

**Publication Number:** 2613843

**IPC:** A61M25/02

**Language of the proceedings:** EN

**Title of invention:**
FIXATION DEVICE

**Patent Proprietor:**
Mölnlycke Health Care AB

**Opponents:**
Essity Hygiene and Health AB / BSN medical GmbH

**Relevant legal provisions:**
EPC Art. 54, 56, 83, 123(2)
RPBA 2020 Art. 13(2)

**Keyword:**
Amendments - added subject-matter (no)
Sufficiency of disclosure - (yes)
Novelty - (yes)
Inventive step - (yes)
Amendment after summons - taken into account (no)

**Decisions cited:**
G 0002/10

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**Beschwerdekammern**

**Boards of Appeal**

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**Case Number: T 0974/23 - 3.2.02**

# D E C I S I O N
# of Technical Board of Appeal 3.2.02
# of 2 September 2025

| | |
|---|---|
| **Appellants:** (Opponents) | Essity Hygiene and Health AB / BSN medical GmbH<br>Schützenstrasse 1-3<br>405 03 Göteborg / 22761 Hamburg (SE) |
| **Representative:** | Cohausz & Florack<br>Patent- & Rechtsanwälte<br>Partnerschaftsgesellschaft mbB<br>Bleichstraße 14<br>40211 Düsseldorf (DE) |
| **Respondent:** (Patent Proprietor) | Mölnlycke Health Care AB<br>Box 6<br>431 21 Mölndal (SE) |
| **Representative:** | Tostmann, Holger Carl<br>Wallinger Ricker Schlotter Tostmann<br>Patent- und Rechtsanwälte Partnerschaft mbB<br>Zweibrückenstrasse 5-7<br>80331 München (DE) |
| **Decision under appeal:** | **Interlocutory decision of the Opposition Division of the European Patent Office posted on 23 March 2023 concerning maintenance of the European Patent No. 2613843 in amended form.** |

**Composition of the Board:**

| | |
|---|---|
| **Chairman** | M. Alvazzi Delfrate |
| **Members:** | S. Dennler |
| | Y. Podbielski |

## Summary of Facts and Submissions

I. The appeal was filed by the opponents against the opposition division's interlocutory decision to maintain the contested patent in amended form on the basis of the patent proprietor's main request.

II. In its decision, the opposition division had found in relation to the main request, *inter alia*, that the claimed invention was sufficiently disclosed, that claim 1 did not contain added subject-matter and that its subject-matter was novel in view of D23 and involved an inventive step starting from either D4 or D8 in combination with D9, even when considering D4a.

D4, D4a, D8, D9 and D23 are the following documents:

**D4** Brochure "3M™ Tegaderm™ Transparentverbände"
**D4a** Brochure "3M Surgical Tapes"
**D8** US 2004/0143220 A1
**D9** WO 2009/075636 A1
**D23** WO 2009/031948 A1

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

The **respondent (the patent proprietor)** requested that the appeal be dismissed, i.e. that the patent be maintained on the basis of the main request. As auxiliary measures, the respondent requested that the patent be maintained on the basis of either auxiliary request 1 or 2, both filed with the reply to the statement of grounds of appeal.

IV. Oral proceedings before the Board were held on 2 September 2025, at the end of which the present decision was announced.

V. The present decision also refers to the following documents:

**D4b** 3M Materials safety data sheet for various 3M™ Tegaderm™ transparent dressings

**D4c** Brochure "Medizinische Rollenpflaster und Fixierverbände - Eine weitreichende Entscheidung in der Pflege", 3M

**D7** Extract from "Thiemes Pflege, Das Lehrbuch für Pflegende in Ausbildung", S. Schewior-Popp *et al.*, 11th edition, Georg Thieme Verlag KG, 2009, pages 788 to 790

**D29** Extract from "Technology of Pressure-Sensitive Adhesives and Products", "Handbook of Pressure-Sensitive Adhesives and Products", I. Benedek and M. M. Feldstein, CRC Press, 2009, pages 6-17 to 6-24

VI. **Claim 1 of the main request** ("claim 1") reads as follows (with the feature numbering used in the decision under appeal and the amendments to claim 1 as originally filed highlighted by the Board):

**1** "*A fixation device (1) for retaining a skin penetrating medical device (2), such as a cannula, on the skin of a patient,*

**1.1** *said fixation device (1) comprising a retaining component (3) including a support layer (4) having an adhesive coating (5),*
***characterised in that***

**1.2** *the fixation device further comprises a landing zone component (6), including a support layer (7) having an adhesive coating (8),*

**1.3** *said landing zone component (6) acting as a skin-contacting component*

**1.4** ~~*and being adapted to be adhesively attached*~~ *wherein the adhesive coating (8) of said landing zone component (6) provide for attachment to the skin around the point of penetration (10),*

**1.5** *wherein said landing zone component (6) has a surface area that is larger than the surface area of the adhesive coating of the retaining component, and*

**1.6** *wherein said retaining component (3)* ~~*being*~~ *is adapted to affix the medical device (2), and* ~~*being adapted to be applied*~~ *is arrangeable on top of the landing zone component (6)*~~*, and*~~ *for at least partially covering the skin penetrating medical device (2), such that the adhesive coating (5) of the retaining component (3) is applied to the support layer (7) of the landing zone component (6),*

**1.7** *wherein the adhesive coating (5) of the retaining component (3) comprises a first adhesive, and the adhesive coating (8) of the landing zone component (6) comprises a second adhesive, said first adhesive being different from said second adhesive, and*

**1.8.1** *wherein the adhesive coating (5) of the retaining component (3) comprises an acrylic adhesive, and*

**1.8.2** *the adhesive coating (8) of the landing zone component (6) comprises a soft skin-friendly adhesive, which is a silicone gel adhesive.*"

VII. The **appellants' arguments** relevant to the present decision can be summarised as follows.

*Added subject-matter*

Claim 1 added subject-matter because features 1.4 and 1.6, which lacked literal basis in the application as filed, impermissibly changed or broadened the original disclosure.

Original claim 1 stated that the landing zone component was adapted to be attached to the skin around the penetration site. By contrast, feature 1.4 merely attributed this function to the adhesive coating, omitting to define the specific adaptation of the landing zone component. Indeed, several features of the specific embodiment shown in Figure 1, cited as basis, had been omitted. Without these features, proper attachment of the landing zone component to the skin could not be achieved. Therefore, these features were inextricably linked to the claimed landing zone component and omitting them from claim 1 constituted an unallowable intermediate generalisation.

Similarly, in feature 1.6, replacing "adapted to be applied", as disclosed in original claim 1, with "arrangeable" had removed the requirement for the retaining component to be specifically adapted to be fixed to the support layer of the landing zone component without shifting. Amending "and at least partially covering" to "for at least partially covering", and deleting the preceding comma, had broadened the original disclosure from actual to merely potential coverage of the skin-penetrating medical device by the retaining component. The application as filed provided no support for these generalisations.

*Sufficiency of disclosure*

The subject-matter of claim 1 was insufficiently disclosed in the patent. The person skilled in the art would not be able to produce a fixation device across the whole scope of the claim without undue burden, as the claimed features did not reliably prevent contact between the retaining component's adhesive coating and the patient's skin. However, the main purpose of the alleged invention was to avoid this contact (see paragraphs [0010] and [0022]).

*Novelty in view of D23*

The subject-matter of claim 1 was not novel in view of D23. D23 disclosed both features 1.1 and 1.6.

D23 (see Figure 3) disclosed that the edge of the medical device (drape 1) was fixed to the support 4 by an adhesive seam 5 comprising an acrylate adhesive (page 7, lines 24-25). This disclosure could only be interpreted as implying the presence of a support layer (i.e. the seam itself) in addition to an acrylic adhesive coating, thus anticipating a retaining component including both a support layer and an adhesive coating, as defined by feature 1.1. Alternatively, the surface of the drape in contact with the adhesive seam could be considered a support layer, since claim 1 did not rule out the support layer of the retaining component being part of the medical device.

Furthermore, the adhesive seam 5 partially covered the bottom of the medical device 1. This anticipated feature 1.6 as well, since this feature did not specify

exactly where the medical device was covered by the retaining component.

*Admittance of the appellants' submissions related to D7, the gel pad embodiment of D4 and pages 18-19 of D9 made during the oral proceedings before the Board*

The appellants' submissions made during the oral proceedings before the Board in relation to arguments based on D7, the reference to the gel pad embodiment of D4 as a starting point of an inventive-step objection and the argument concerning the replacement of the gel pad with a silicone gel adhesive, as well as the reliance on pages 18-19 of D9 concerning the issue of whether D9 disclosed that a medical device could be affixed to the dressing, should be admitted in the appeal proceedings.

D7 was a textbook extract that merely reflected common general knowledge. Moreover, D7 had already been discussed in the opposition proceedings.

The new inventive-step objection starting from the gel pad embodiment of D4 (see page 17) had been prompted by the Board's preliminary opinion set out in its communication under Article 15(1) RPBA (see in particular point 8.4), according to which the person skilled in the art starting from D4 would not have considered using an adhesive other than an acrylate polymer adhesive.

The reference to pages 18-19 of D9 was in response to the Board's statement in its communication (see point 8.4) that D9 contained no disclosure or suggestion that a medical device could be affixed to the dressing.

*Inventive step starting from D4 or D8*

The subject-matter of claim 1 did not involve an inventive step starting from D4 or D8.

D4 disclosed (see, for example, picture 6 on page 9) a fixation device comprising a landing zone component (the Tegaderm transparent dressing) and a retaining component (one of the Medipore strips). D4a to D4c indicated that these parts contained acrylic adhesives. As the Tegaderm dressing and Medipore strips were different commercial products, the acrylic adhesives were not identical. Moreover, the adhesive used in D4 for the landing zone component was explicitly described as hypoallergenic and skin-friendly (see page 2 and penultimate page). Therefore, the subject-matter of claim 1 only differed from the device of D4 in that the adhesive coating of the landing zone component comprised a silicone gel adhesive (feature 1.8.2).

Accordingly, the fixation device of D4 provided for the same technical effects as discussed in paragraph [0029] of the contested patent, and a silicone gel adhesive was just one example of an adhesive that could guarantee these effects.

Therefore, the objective technical problem could be considered to merely be the provision of an alternative fixation device that had similar effects on skin. Starting from D4 and confronted with this problem, the person skilled in the art would have arrived at the subject-matter of claim 1 without any inventive skill. The same conclusion was reached even if the objective technical problem was formulated more ambitiously - to the respondent's advantage - as providing a dressing

that was particularly skin-friendly and well adapted to patients with sensitive skin.

Indeed, when faced with either of these technical problems, the person skilled in the art would have consulted D9. Like D4, D9 disclosed a dressing for protecting the skin around a skin-penetrating medical device. In addition, D9 explicitly stated that the dressing could also be used to affix the medical device, for example a gastrostomy feeding tube (see the first paragraph on page 19). In any case, to some extent at least, the medical device was fixed in place by projecting through the hole in the dressing. Moreover, certain embodiments (see Figure 7) had secondary slits forming wings that adhered to the medical device's outer surface and thus retained it. Moreover, D9 also emphasised the strong adhesion to the skin permitted by silicone gel adhesives (page 9, line 21 - page 10, line 6), which rendered the dressing of D4 suitable for retaining a medical device. D9 even suggested using the same "Wacker SilGel 612" silicone gel adhesive (see page 10, line 22) which was also disclosed in paragraph [0029] of the contested patent.

More generally, as reflected in D29, the person skilled in the art was well aware, at the priority date of the contested patent, of the possibility of using silicone gel adhesives as a skin-facing layer in dressings, and of the associated benefits.

In view of this, the person skilled in the art would have seriously considered using a silicone gel adhesive as an alternative adhesive to the adhesive used in the Tegaderm transparent dressing of D4.

When doing so, they would naturally have kept the acrylic adhesive used in the Medipore strips unchanged. The retaining component anticipated by these strips was not a distinguishing feature and, as such, remained unaffected by the solution to the technical problem. Furthermore, as the Tegaderm transparent dressing and the Medipore strips served different purposes, the person skilled in the art would not reasonably have considered using the same adhesive for both. The Medipore strips were primarily applied to the Tegaderm transparent dressing, rather than to the patient's skin directly. Moreover, the issues concerning the removal of the dressing from patients with fragile skin mentioned on page 11 of D4 only related to the Tegaderm transparent dressing and not the strips.

Similar reasoning applied when starting from D8. As with D4, the subject-matter of claim 1 only differed from the fixation device disclosed in D8 in that the adhesive coating of the landing zone component comprised a silicone gel adhesive instead of an acrylic adhesive. For the same reasons as discussed when starting from D4 as closest prior art, the person skilled in the art starting from D8 would also have arrived at the subject-matter of claim 1 without exercising an inventive step.

VIII. The **respondent's arguments** relevant to the present decision can be summarised as follows.

*Added subject-matter*

Claim 1 did not contain added subject-matter. Features 1.4 and 1.6 constituted either alternative wordings or simple clarifications of the features of original claim 1, and did not change the originally

disclosed technical content. The person skilled in the art would directly and unambiguously derive features 1.4 and 1.6 from the application as filed. The further features referred to by the appellants were not inextricably linked to the features of claim 1.

*Sufficiency of disclosure*

The invention defined in claim 1 was sufficiently disclosed in the contested patent. Although occasional contact of the retaining component's adhesive with the skin was indeed to be avoided according to the patent, this did not prevent a person skilled in the art from making the claimed fixation device.

*Novelty in view of D23*

The appellants' novelty objection in view of D23 relied on a contrived construction of claim 1. D23 failed to disclose at least features 1.1 and 1.6. Therefore, the subject-matter of claim 1 was novel over D23.

*Admittance of the appellants' submissions related to D7, the gel pad embodiment of D4 and pages 18-19 of D9 made during the oral proceedings before the Board*

These submissions could have been filed much earlier. There was no reason or exceptional circumstances that could justify their admittance at such a late stage of the appeal proceedings.

*Inventive step starting from D4*

The subject-matter of claim 1 was inventive starting from D4, even when considering D9.

D4 itself did not disclose which adhesive was used for the transparent dressing component and for the strips, let alone that different adhesives were used. Even assuming that D4a to D4c related to the dressing of D4 - which was disputed - this would at most indicate the use of polyacrylate adhesive in all of them. Therefore, the subject-matter of claim 1 differed from the dressing kit of D4 at least on account of features 1.7 and 1.8.2.

These distinguishing features solved the objective technical problem of providing a fixation device that would securely affix a medical device without causing discomfort to fragile skin or after long-term use.

This problem was already solved in D4. Therefore, the person skilled in the art starting from this document would not have been motivated to look for an alternative. D4 already disclosed how to use the disclosed dressing kit with patients having sensitive skin (see the last tip on page 11). Moreover, D4a disclosed that the polyacrylate adhesive allegedly used in D4 was soft and skin-friendly, and therefore adapted for fragile skin and long-term use.

Even if the person skilled in the art starting from D4 had searched for an alternative solution, they would not have consulted D9, let alone been motivated by that document to use a silicone gel adhesive. The dressing disclosed in D9 was designed only to protect the skin around a skin-penetrating device, not to retain the device on the skin. D9 did not disclose or suggest that the dressing, with its silicone gel adhesive, would be able to withstand the load of the device. The first paragraph on page 19 merely explained that the disclosed dressing could help protect the patient's

skin when gastrostomy feeding tubes were affixed; however, it did not suggest that the dressing could affix the tubes itself.

In any case, both the transparent dressing and the strips disclosed in D4 were intended for application to the patient's skin. Therefore, even if the person skilled in the art had been motivated to use a soft, skin-friendly silicone gel adhesive, they would have been motivated to use it for the strips as well. However, this would not have led to the subject-matter of claim 1.

## Reasons for the Decision

### 1. Subject-matter of the contested patent

The contested patent relates to an adhesive fixation device for retaining a skin-penetrating medical device, such as a cannula, on a patient's skin (see paragraphs [0007] and [0008]).

Figure 1, reproduced below, shows an example of a fixation device according to claim 1. The device (1) comprises a landing zone component (6) and a retaining component (3), each of which includes a support layer (7 or 4) having an adhesive coating (8 or 5).

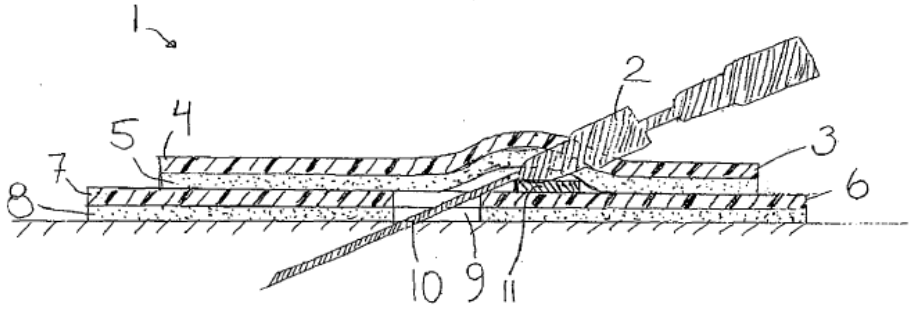


Fig 1

As defined in claim 1, the landing zone component (6) acts as a skin-contacting element, wherein the adhesive coating (8) of the landing zone component provides for attachment to the skin around the point of penetration (10) - in the illustrated embodiment via an opening (9). The landing zone component has a larger surface area than the adhesive coating of the retaining component. The retaining component (3) is adapted to affix the skin-penetrating medical device (2) and is arrangeable on top of the landing zone component for at least partially covering the medical device (2), such that the adhesive coating (5) of the retaining component is applied to the support layer (7) of the landing zone component.

A key aspect of the claimed invention is the use of different adhesives for the two components: a soft, skin-friendly silicone gel adhesive for the landing zone component and an acrylic adhesive for the retaining component, which is stronger but aggressive to the skin. This makes the fixation device skin-friendly and easy to apply and remove while ensuring a secure fixation of the skin-penetrating device in place (see paragraphs [0008], [0017], [0022]-[0025]).

## 2. Added subject-matter

Contrary to the appellants' view, claim 1 does not contain added subject-matter.

Article 123(2) EPC does not require literal support of an amendment. Rather, the relevant test is the "gold standard" (see G 2/10; OJ 2012, 376) that the Enlarged Board originally formulated in G 3/89, namely that any amendment can only be made within the limits of what the person skilled in the art would derive directly and

unambiguously, using common general knowledge, and seen objectively and relative to the date of filing, from the whole of the application as filed (see G 3/89; OJ 1993, 117). After the amendment the person skilled in the art may not be presented with new technical information (see G 2/10, Reasons 4.5.1).

Although they have no literal basis in the application as filed, features 1.4 and 1.6 are directly and unambiguously derivable from the original disclosure; the amendments to original claim 1 that these features constitute merely amount to clarifications or alternative phrasing that do not extend beyond the original disclosure.

*2.1 Feature 1.4*

Original claim 1 states that the landing zone component is adapted to be adhesively attached to the skin around the point of penetration. The appellants contended that, by merely attributing the attachment function of the landing zone component to its adhesive coating and omitting the specific adaptation of the landing zone component, feature 1.4 added subject-matter.

The Board disagrees. Stating in feature 1.4 that it is the adhesive coating of the landing zone component that provides for the adhesive attachment does not add subject-matter, but merely makes explicit what the person skilled in the art would understand from the disclosure in original claim 1 of a skin-contacting component with an adhesive coating for adhesive attachment to the skin, namely that it is the adhesive that enables the component to be adhesively attached to the skin. Hence, claim 1 as originally filed already provides a basis for feature 1.4.

Even considering, for the sake of argument, that the basis for feature 1.4 is rather to be found in the embodiment of Figure 1, this would not lead to the conclusion that the feature represents an unallowable amendment. The further features pointed to by the appellants which are disclosed for the particular embodiment shown in Figure 1 of the original application but are not defined in claim 1 are not inextricably linked with feature 1.4 or any other features of claim 1. Notably, the fastening means 11 and the opening 9 are described in the original application as optional features that merely facilitate the use of the device (see, for example, page 6, lines 4-6: "By arranging a fastening means [...] the application of the landing zone component can be essentially facilitated"; page 10, line 20: "the landing zone component preferably comprises an opening"; emphasis added by the Board). Furthermore, the appellants' allegation that proper attachment to the skin, especially for embodiments containing a silicone gel adhesive, would require the landing zone component's support layer and adhesive coating to be co-extensive, in particular up to the opening's edge, is not reflected as a mandatory limitation in the original disclosure. Therefore, the omission of these features from claim 1 does not constitute an unallowable intermediate generalisation.

*2.2 Feature 1.6*

The appellants argued that, by stating that the retaining component is "arrangeable" on top of the landing zone component, instead of being "adapted to be applied" thereto as disclosed in original claim 1, feature 1.6 had removed the requirement that the

retaining component be specifically adapted to be fixed to the landing zone component's support layer without shifting, and therefore added matter.

The Board disagrees. Feature 1.6 specifies that the retaining component is arrangeable, i.e. adapted to be arranged, on top of the landing zone component "such that the adhesive coating (5) of the retaining component (3) is applied to the support layer (7) of the landing zone component (6)". Therefore, when considered in the context of feature 1.6 as a whole, the term "arrangeable" does not dispense with the fixation of the retaining component or permit its subsequent shifting once it has been arranged on top of the landing zone component and its adhesive coating has been applied to the support layer of the landing zone component, in line with original claim 1. The Board therefore sees there no extension of the original disclosure, even if the term "arrangeable" is not used in the application as filed.

The appellants also argued that the change from "and at least partially covering" to "for at least partially covering" in feature 1.6 had inadmissibly broadened the original disclosure from a retaining component that actually covered the skin-penetrating medical device to one that merely allowed for it.

The Board also disagrees. It is true that the "for"-wording in feature 1.6 only defines the suitability of the retaining component for at least partially covering the skin-penetrating medical device. However, this merely reflects the fact that the medical device is not part of the claimed fixation device, as the person skilled in the art would also understand from the

original disclosure. Thus, this amendment does not add matter either.

## 3. Sufficiency of disclosure

Contrary to the appellants' view, the contested patent discloses the invention as claimed in the main request in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

The appellants' argument that the claimed fixation device might be used in a way that brings the adhesive coating of the retaining component into contact with the skin - indeed, something that the patent teaches should be avoided, see paragraphs [0010] and [0022] - relates merely to an unintended and undesired use of the device. Not only would the person skilled in the art easily recognise and avoid this situation, but, most importantly, the possibility of misusing the claimed fixation device would not prevent them from making a fixation device as claimed.

## 4. Novelty in view of D23

Contrary to the appellants' view, the subject-matter of claim 1 is novel in view of D23.

4.1 The appellants' argument that Figure 3 of D23, reproduced below, discloses a device comprising features 1.1 and 1.6 relies on an artificial and unconvincing mapping of these features onto the device in question.

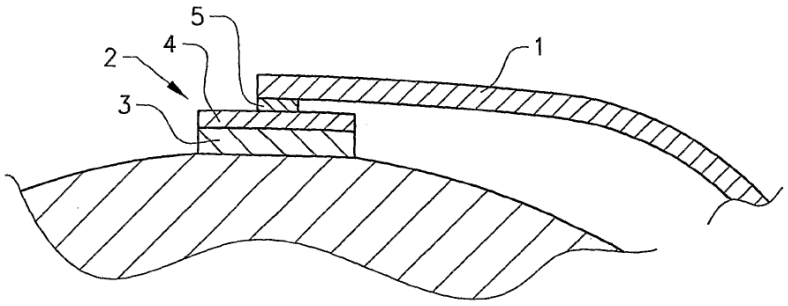


FIG. 3

4.2 D23 discloses that the "narrow adhesive seam" 5 used to secure the edge of the drape 1 to the support 4 in this device "can comprise any suitable adhesive" (page 7, last paragraph). However, contrary to the appellants' view, D23 does not directly and unambiguously disclose that this seam comprises a support layer in addition to the disclosed adhesive, which would be necessary to anticipate feature 1.1. Moreover, the person skilled in the art would understand from claim 1 that the support layer of the retaining component as defined by feature 1.1 cannot be a portion of the skin-penetrating medical device, as asserted by the appellants in another line of argument. The medical device is not part of the claimed fixation device; it is merely covered by the retaining component during use. Therefore, the surface of the drape 1 in contact with the adhesive seam cannot be considered a support layer as defined in feature 1.1.

4.3 Furthermore, as shown in Figure 3, the adhesive seam 5 is designed to be arranged, in use, between the support 4 and the retained drape 1. In other words, as conceded by the appellants, the seam 5 is underneath the drape 1 and in contact with its lower surface. Therefore, the person skilled in the art would not consider it to be arranged "on top of" the support 4

for at least partially "covering" the drape, as would be required to anticipate feature 1.6.

## 5. Admittance of the appellants' submissions related to D7, the gel pad embodiment of D4 and pages 18-19 of D9 made during the oral proceedings before the Board

At the oral proceedings before the Board, during the debate on whether the subject-matter of claim 1 involved an inventive step when starting from D4, the appellants made the following submissions:

(a) they presented arguments based on D7, according to which D7 provided evidence that dressing kits like those disclosed in D4 were routinely used to fix intravenous tubing to a patient's skin. D7 also showed how the different parts of these dressings kits were used in practice;

(b) they referred to the gel pad embodiment of D4 shown on page 17 as a starting point of a new inventive-step objection, based on the argument that the person skilled in the art would replace the gel pad with a silicone gel adhesive;

(c) they referred to pages 18-19 of D9 concerning the issue of whether D9 disclosed that a medical device could be affixed to the dressing.

The respondent disputed the admittance of these submissions at such a late stage of the appeal proceedings.

5.2 The appellants conceded that they had not referred to D7, the gel pad embodiment shown on page 17 of D4 and pages 18-19 of D9 in their submissions on appeal until

the oral proceedings before the Board. Therefore, these submissions undisputedly constitute amendments to their appeal case.

According to Article 13(2) RPBA, any amendment to a party's appeal case made after notification of a communication under Article 15(1) RPBA, hence at the oral proceedings before the Board, must, in principle, not be taken into account unless there are exceptional circumstances, which have been justified with cogent reasons by the party concerned.

5.3 The fact that D7 may provide evidence of common general knowledge, illustrating that the dressings like those disclosed in D4 were routinely used to fix intravenous tubing to a patient's skin - a point which is not in dispute - does not constitute such exceptional circumstances. Nor does the mere fact that D7 was already discussed during the opposition proceedings.

The appellants argued that the new inventive-step objection starting from the gel pad embodiment of D4 had been prompted by the Board's preliminary opinion set out in its communication under Article 15(1) RPBA, in particular in point 8.4, according to which the person skilled in the art starting from D4 would not have considered using an adhesive other than an acrylate polymer adhesive. However, in this respect, the Board's view did not deviate from the opposition division's corresponding finding in the decision under appeal (see last paragraph of Reasons 2.5.3 on page 16).

Therefore, the appellants did not put forward any exceptional circumstances, and the Board saw none, that would have justified the admittance of submissions (a)

and (b) at that late stage of the appeal proceedings. Consequently, the Board decided not to admit these submissions under Article 13(2) RPBA.

5.4 With regard to submission (c), the appellants explained that the reference to pages 18-19 of D9 had been made to counter the Board's statement in its communication under Article 15(1) RPBA (see point 8.4) that D9 contained no disclosure or suggestion that a medical device could be affixed to the dressing disclosed in D9. In particular, the first paragraph on page 19 indicated that the dressings disclosed in D9 could be used, among other things, "for affixing and avoid leakages with percutaneous endoscopic gastrostomy (PEG) feeding tubes". According to the appellants, this disclosure contradicted the Board's statement.

The Board accepts this justification and considers the reference to pages 18-19 of D9 to be a further argument that builds on and refines the inventive-step objections based on the combination of D4 or D8 with D9 that the appellants filed in their statement of grounds of appeal. Therefore - regardless of its merits - the Board decided to admit this reference to pages 18-19.

## 6. Inventive step starting from D4

Contrary to the appellants' view, the subject-matter of claim 1 involves an inventive step starting from D4.

6.1 It is common ground that D4 discloses a fixation device (see, for example, the Tegaderm IV dressings 1633 and 1635 shown on pages 5 and 9) for retaining a medical device (an intravenous catheter or cannula) on the skin of a patient. This device comprises a landing zone component (the Tegaderm transparent dressing) and a

retaining component (each of the Medipore strips provided with the transparent dressing). Each component includes a support layer with an adhesive coating.

While the Medipore strips can be applied directly to the skin to secure the catheter (see picture 4 on page 7), D4 discloses that the strips can also be arranged on top of the transparent dressing, after it has been applied to the skin, to at least partially cover and thus retain the catheter (see picture 6 on page 9).

Therefore, D4 discloses features 1 to 1.6.

6.2 The parties disagree as to whether D4 also discloses feature 1.7. The Board agrees with the respondent that D4 does not disclose this feature, even implicitly.

D4 mentions a hypoallergenic and skin-friendly adhesive (page 2: "hypoallergene Klebstoff"; page 17: "haut-freundlich") and a pressure- and heat-sensitive adhesive (page 11: "druck- und wärmeempfindlichen Klebstoff"). However, it does not provide any information about the adhesive's chemical composition. Nor does it contain any indication that different adhesives are used for the Tegaderm transparent dressing and the Medipore strips. Contrary to the appellants' argument, the fact that these components have different trade names (Tegaderm and Medipore), different pharmaceutical registration numbers (see the last page of D4) and possibly different functions does not directly and unambiguously discloses that they contain different adhesives.

The appellants asserted that the adhesives used in D4 were implicitly those disclosed in D4a to D4c: an

acrylate polymer for the Tegaderm 1633 and 1635 dressings (see page 1 of D4b), and polyacrylate for the Medipore strips (see the table on page 1 of D4a, and page 6 of D4c). Hence, both were acrylic adhesives. Assuming that the Medipore strips referred to in D4a and D4c were the same as those disclosed in D4 - a point in dispute between the parties - this would indeed disclose feature 1.8.1.

However, this would not directly and unambiguously disclose feature 1.7 since, while not all acrylate polymers are polyacrylate, polyacrylate is an acrylate polymer. Therefore, it could not be ruled out that polyacrylate be also used for the Tegaderm 1633 and 1635 dressings, meaning that the two adhesives used in the fixation device of D4 would be identical - contrary to what feature 1.7 requires.

6.3 On the other hand, it is common ground that D4 does not disclose that the adhesive coating of the landing zone component comprises a soft silicone gel adhesive, as required by feature 1.8.2.

6.4 Therefore, the subject-matter of claim 1 differs from the fixation device disclosed in D4 by both features 1.7 and 1.8.2. In substance, this means that the adhesive coating of the landing zone component comprises a soft silicone gel adhesive; adopting such a different adhesive for the landing zone component would necessarily satisfy feature 1.7.

6.5 Given this difference, the appellants proposed two different formulations of the objective technical problem: the provision of an alternative fixation device that had similar effects on skin, or the provision of a dressing that was particularly skin-

friendly and well adapted to patients with sensitive skin. The appellants argued that the person skilled in the art, starting from D4 and faced with either of these technical problems, would have replaced the acrylic adhesive of the Tegaderm transparent dressing by a silicone gel adhesive without any inventive skill.

It is true that, as argued by the appellants, the fact that D4 discloses that the adhesive coating of the Tegaderm transparent dressing is skin-friendly, as stated above, or that D4 teaches how to the disclosed fixation device should be used with patients having sensitive skin (see the last tip on page 11) would not preclude the person skilled in the art from seeking an alternative adhesive for the Tegaderm transparent dressing that is equally or even more skin-friendly.

However, even accepting either of the appellants' formulations of the objective technical problem, the assertion that the person skilled in the art starting from D4 and faced with this problem would have arrived at the subject-matter of claim 1 without hindsight and without inventive skill is not convincing.

6.5.1 Firstly, the disclosure in D4a that polyacrylate - the adhesive used for the Medipore strips in D4, according to the appellants - is soft and skin-friendly, coupled with the absence of any disclosure or suggestion of feature 1.7 in D4, would rather have led the person skilled in the art to use the same polyacrylate adhesive for the Tegaderm transparent dressing, rather than seeking a further alternative.

6.5.2 Secondly, the person skilled in the art faced with either of these technical problems would not have been motivated by D9 to replace the acrylic adhesive coating

of the Tegaderm transparent dressing with a silicone gel adhesive.

This is because, contrary to the appellants' argument, the function of the dressing disclosed in D9 is merely to protect the skin around objects projecting out from it. The silicone gel adhesive disclosed in D9 is described only as being sufficiently adhesive to "attach the dressing securely to the skin" and to withstand "all the normal loadings to which dressings are subjected" (page 9, lines 7-9). However, D9 contains no disclosure or suggestion that a medical device could be affixed to such a dressing. The first paragraph on page 19, to which the appellants referred during the oral proceedings before the Board, merely explains that the dressing could help protect the patient's skin and prevent leakage when a gastrostomy feeding tube is affixed on the patient; however, the person skilled in the art reading this passage in the context of the entire disclosure of D9 would not interpret it as disclosing or suggesting that the dressing could affix the tube itself. Similarly, the fact that the skin-penetrating device projects through the hole in the dressing does not fix the device in place. Nor do the wings formed by the secondary slits in the embodiments referred to by the appellants (see, for example, Figure 7), which are described only as a way of accommodating projecting objects of different diameters (see page 15, lines 18-20).

Although D9 emphasises the strong adhesion to the skin permitted by silicone gel adhesives (page 9, line 21 - page 10, line 6), this is only to explain how the dressing of D9, with such a soft adhesive, can be attached securely to the skin "in spite of the fact that the strength of the adhesive attachment of the

silicone gel to the skin is not in itself so strong" (page 9, lines 25-27). This does not disclose or suggest that the dressing would be able to withstand the load of a device affixed to it, and the person skilled in the art would not infer this from D9 in the absence of any such information.

Therefore, without the benefit of hindsight, the person skilled in the art, even if they had consulted D9, would not have replaced the acrylic adhesive that the appellants assert is used in D4 in the Tegaderm transparent dressing with the silicone gel adhesive disclosed in D9.

6.5.3 It is immaterial that D9 mentions the same "Wacker SilGel 612" silicone gel adhesive (see page 10, line 22) as paragraph [0029] of the contested patent, and likewise immaterial that, at the priority date of the contested patent, the person skilled in the art may have been aware - for example, from D29 - of the skin-friendliness of silicone-based adhesives and their advantages as skin-facing layers. The question is not whether a silicone gel adhesive could be used for the landing zone component of D4, but whether the person skilled in the art starting from D4 would have done so.

When seeking alternative adhesives that are equally or more skin-friendly than acrylic adhesives, the person skilled in the art would have only considered adhesives known to be suitable to withstand, like acrylic adhesives, the additional load that a medical device retained by the retaining component as disclosed in D4 would exert on the dressing. Neither D9 nor D29 provides such a teaching.

6.5.4 Thirdly, D4 discloses that both the Tegaderm transparent dressing and the Medipore strips are intended for application to the patient's skin (see picture 4 on page 7 and picture 6 on page 9). The appellants' contention that the Tegaderm transparent dressing and the Medipore strips serve different purposes and that the Medipore strips are primarily applied to the Tegaderm transparent dressing rather than directly to the patient's skin does not alter nor contradict the fact that D4 presents each as skin-applied.

Accordingly, even if the person skilled in the art were prompted by D9 to use a soft, skin-friendly silicone gel adhesive, they would implement this adhesive for both the Tegaderm transparent dressing and the Medipore strips. However, such a uniform substitution would not lead to the subject-matter of claim 1, because the resulting strips would then not comprise an acrylic adhesive as required by feature 1.8.1.

Contrary to the appellants' argument, the fact that the retaining component anticipated by the strips is not a distinguishing feature of claim 1 - and therefore does not enter the formulation of the objective technical problem - does not preclude the person skilled in the art from modifying it, or other aspects of the fixation device of D4 used as the starting point, in the course of solving that problem.

## 7. Inventive step starting from D8

Contrary to the appellants' view, the subject-matter of claim 1 involves an inventive step starting from D8.

The appellants' inventive-step objection based on D8 as the starting point in combination with D9 is based on a line of argument similar to that of the inventive-step objection starting from D4. For similar reasons, it is not convincing.

As acknowledged by the appellants, D8 only discloses acrylic-based adhesives. Furthermore, contrary to the appellants' argument, the disclosure of four distinct adhesive layers in D8 does not directly and unambiguously disclose or suggest that the first to fourth adhesives are or should be different.

For the same reasons as discussed for the objection starting from D4, the person skilled in the art starting from D8 would not, without the benefit of hindsight, have arrived at the subject-matter of claim 1 in an obvious manner.

## 8. Conclusion

None of the appellants' objections considered on appeal prejudice the maintenance of the contested patent as amended on the basis of the main request, i.e. as held by the opposition division to meet the requirements of the EPC.

## Order

## For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

G. Magouliotis M. Alvazzi Delfrate

Decision electronically authenticated