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**Datasheet for the decision
of 28 May 2021**

Case Number: T 1468/16 - 3.2.02

Application Number: 09718606.8

Publication Number: 2271381

IPC: A61M1/00, A43B13/40

Language of the proceedings: EN

Title of invention:

OFFLOADING AND REDUCED-PRESSURE TREATMENT

Patent Proprietor:

KCI Licensing, Inc.

Opponent:

Smith and Nephew, Inc.

Headword:

Relevant legal provisions:

EPC Art. 54(1), 54(2), 56, 100(a), 100(b)

Keyword:

Grounds for opposition - insufficiency of disclosure (no) -
novelty - (yes) - inventive step - (yes)

Decisions cited:

T 1642/12, T 2221/10

Catchword:



Beschwerdekammern

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Case Number: T 1468/16 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 28 May 2021

Appellant: KCI Licensing, Inc.
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Respondent: Smith and Nephew, Inc.
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Representative: HGF
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Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
22 April 2016 concerning the maintenance of
European Patent No. 2271381 in amended form**

Composition of the Board:

Chairman M. Alvazzi Delfrate
Members: D. Ceccarelli
C. Schmidt

Summary of Facts and Submissions

I. The patent proprietor and the opponent have appealed against the Opposition Division's decision that, account being taken of the amendments made by the patent proprietor according to the second auxiliary request, European patent No. 2 271 381 and the invention to which it relates met the requirements of the EPC. The decision was posted on 22 April 2016.

The patent was opposed on the grounds of insufficient disclosure, lack of novelty and lack of inventive step.

II. Oral proceedings took place on 28 May 2021 by videoconference.

The appellant/patent proprietor ("the proprietor") requested that the decision under appeal be set aside and that the patent be maintained as granted (main request) or on the basis of one of the first or second auxiliary requests filed on 31 January 2020.

At the beginning of the oral proceedings, the appellant/opponent ("the opponent") requested that the decision under appeal be set aside and that the patent be revoked; however, at the end of the oral proceedings before the decision was announced, the opponent withdrew its appeal.

III. The following documents are mentioned in this decision:

E2: US-A-2005/0020955
E3: US-A-2002/0082567
E4: US-A-5,761,834
E6: WO-A-2006/091735

E8: WO-A-2009/021523
E10: US-B-7,214,202
E11: WO-A-01/85248
E12: US-A-2004/0006319

IV. Claim 1 of the patent as granted reads as follows:

"An offloading and reduced-pressure treatment device (102) comprising:

a plantar member (104), the plantar member (104) formed from an offloading manifold material; wherein the offloading manifold material (116) comprises:

a support layer (128) having a first surface and a second surface,
a pressure-transmitting layer (134) having a first surface (136) and a second surface (138), the first surface of the pressure-transmitting member coupled to the second surface of the support layer (128), and
a first barrier layer (140) having a first surface (142) and a second surface, the first surface of the first barrier layer coupled to the second surface (138) of the pressure-transmitting layer (134); and

a reduced-pressure interface fluidly coupled to the pressure-transmitting layer (134) of the plantar member (104)."

Claims 2 to 10 are dependent claims.

- V. The proprietor's arguments, where relevant to the decision, may be summarised as follows:

Novelty

The Opposition Division's conclusion in the impugned decision that the subject-matter of claim 1 of the patent as granted lacked novelty over E2 and E3 was incorrect.

Claim 1 defined a plantar member formed from an offloading manifold material, the offloading manifold material comprising a support layer. The Opposition Division's view that the support layer would be anticipated by "any layer providing a support function, i.e. an increased resistance to deformation to the surface of the device, even if minor" was too broad and was not consistent with the meaning the person skilled in the art would give the phrase, or with the overall teaching of the patent. In view of paragraphs [0010], [0015] and [0017] in particular, the requirement in claim 1 for an offloading manifold material was for a layer which offloaded at least a significant portion of the patient's weight in order to assist healing.

The Opposition Division's conclusion that the subject-matter of claim 1 of the patent as granted lacked novelty was also based on an incorrect interpretation of the term "coupled" in the claim. While paragraph [0013] of the patent disclosed that this term included two parts formed from the same material, this disclosure did not apply to the term as used in claim 1 because such a construction contradicted the plain meaning of the claim. Section II.A.6.3.1 of "Case Law of the Boards of Appeal", 9th edition 2019, cautioned that interpreting claims in light of the description

had limitations and that a discrepancy between the claims and description was not a valid reason to ignore the clear linguistic structure of a claim feature which in itself imparted clear credible technical teaching to the skilled reader (as also found in decision T 2221/10). Claim 1 of the patent as granted required a support layer having first and second surfaces, and a pressure-transmitting layer having first and second surfaces, where the first surface of the pressure-transmitting layer is coupled to the second surface of the support layer. Claim 1 thus explicitly required both the support layer and pressure-transmitting layer to have surfaces. Those surfaces, which were the outside of the respective layers, were coupled together. By virtue of the definition of the surfaces, the general meaning of the term "coupled" as given in paragraph [0013] of the patent was limited. Therefore, claim 1 clearly required two distinct components, each forming one of the layers.

E2 did not disclose a treatment device with a plantar member formed from an offloading manifold material as required by claim 1 of the patent as granted.

E3 did not disclose a treatment device with a plantar member formed from an offloading manifold material, a support layer or a pressure-transmitting layer as required by claim 1 of the patent as granted.

Inventive step

Starting from E2 or E3, the distinguishing feature of claim 1 of the patent as granted, i.e. providing a plantar member formed from an offloading manifold material, addressed the objective technical problem of improving the treatment of a wound on a plantar region

of a foot. The problem formulated by the opponent, concerned with relieving pressure around the wound, was too narrow as it included a pointer to the claimed solution. The prior art provided no suggestion of implementing the distinguishing feature in the treatment device from either E2 or E3. Moreover, the implementation would go against the primary purpose of these documents, which was to provide a dressing that was flexible enough to easily wrap around the foot.

Starting from E10 the person skilled in the art would not be prompted to consider adding an extra support layer between the wound and the foam dressing of the treatment device from E10 in view of the teaching of a sheet of elastic material 38 from E11 or of a membrane 219 from E12, which were not support layers within the meaning of claim 1 of the patent as granted.

Starting from E4, this document did not disclose a reduced-pressure interface fluidically coupled to the pressure-transmitting layer of the plantar member as recited in claim 1 of the patent as granted, but instead used positive pressure in an air bladder 64 to support the user. The person skilled in the art would not contemplate using the air bladder to transmit reduced pressure because doing so would remove the function of that component by sucking air out of it.

Sufficiency of disclosure

The Opposition Division had correctly decided that the invention as defined in claim 1 of the patent as granted was sufficiently disclosed. The opponent had not raised any points which could cast doubt on the correctness of the impugned decision in that respect.

VI. The opponent's arguments, where relevant to the decision, may be summarised as follows:

Novelty

The proprietor's assertion that an offloading manifold layer was a requirement for a layer that offloaded at least a significant portion of the patient's weight in order to assist healing was not correct. The patent did not specify how much pressure should be offloaded from the patient or that the offloading function assisted in healing. It was only stated that pressure from around the wound was removed. A cushioning effect was merely optional (paragraph [0015]). Even a small reduction in pressure on the wound assisted in healing, at least to some degree. Moreover, paragraph [0017] attributed the offloading function to a thin coating. Therefore, any layer resisting some weight or providing a support function, even if only small, would provide an offloading function and therefore would be a support layer, as correctly found by the Opposition Division in the impugned decision.

According to established case law (decision T 1646/12 and "Case Law of the Boards of Appeal", 9th edition 2019, II.A.6.3.3) the description could give a special meaning to a term in a claim. Paragraph [0013] of the patent stated that the term "coupled" included "two or more components that are continuous with one another by virtue of each of the components being formed from the same piece of material." By virtue of this special definition, which just followed the description (paragraph [0012]) of the support layer, the pressure-transmitting layer and the first barrier layer as defined in claim 1 of the patent as granted, the claimed subject-matter had to encompass two parts

formed from the same piece of material. This was confirmed by paragraph [0017], which expressly stated that, in an embodiment, the support layer and the pressure-transmitting layer could be a single layer. Although the claim required the support layer and the pressure-transmitting layer to have first and second surfaces, the first surface of the pressure-transmitting layer and the second surface of the support layer could be present at a boundary between the two layers when these layers were integrally formed. The layers had been mentioned as providing a functional rather than a mere physical definition of the subject-matter. Therefore, the construction of the term "coupled" to include two parts formed from the same material did not contradict the plain meaning of claim 1. According to "Case Law of the Boards of Appeal", 9th edition 2019, II.A.6.3.4, no implicit restrictive feature should be read into the claim if not suggested by its explicit wording.

In view of these interpretations, both E2 and E3 clearly deprived the subject-matter of claim 1 of novelty.

Inventive step

Even if it were found that E2 failed to disclose "a plantar member formed from offloading material" or a "support layer", claim 1 of the patent as granted would still lack an inventive step in view of E2.

The technical effect of these features was to remove pressure from around a wound being treated. The objective technical problem was therefore to improve relief of pressure around the wound being treated. The problem formulated by the proprietor, i.e. improving

the treatment of a wound on a plantar region of a foot, was too broad.

Faced with the objective technical problem, the person skilled in the art would either add another layer or improve wound facing layer 16a from E2 in order to make it able to remove pressure from around the wound. A support layer for this purpose was also disclosed in E6 and E8.

The proprietor's argument that a stiff and rigid support layer would go against the primary purpose of E2 was irrelevant, since claim 1 did not specify that the support layer had to be strong and rigid. The flexibility of the treatment device of E2 was derived from its shape. Bulking up the layers would not decrease flexibility. Moreover, E6 did not disclose a rigid support layer.

The same considerations applied when starting from E3.

It would also be obvious to modify the treatment device disclosed in E10 to include a further layer between its foam dressing and the wound. An additional sheet of elastic material (38) as taught in E11 or a membrane (219) as taught in E12 would provide sufficient support and would result in a device as claimed.

The subject-matter of claim 1 of the patent as granted was not inventive when starting from E4. It would be obvious to modify E4 to change the pump and pressure relief valves for a suction pump for applying reduced pressure. This technique was commonly used to help heal wounds so the person skilled in the art would simply consider it an alternative to the air bladder disclosed in E4.

Sufficiency of disclosure

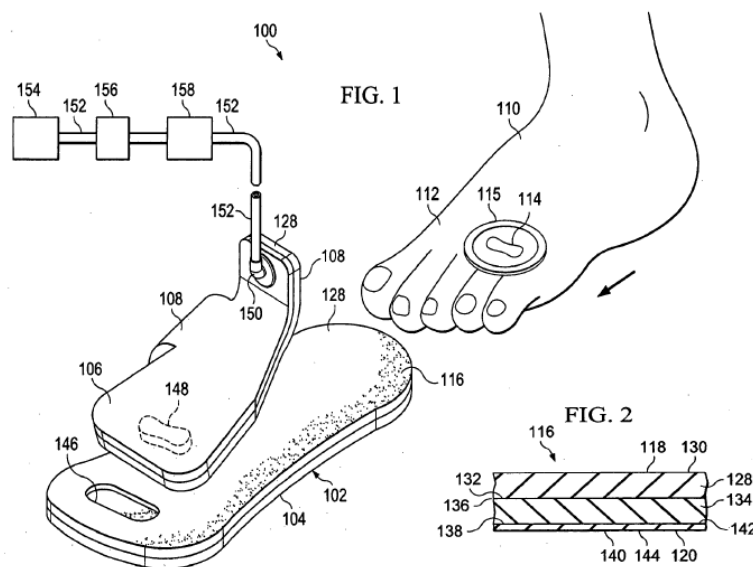
Claim 1 lacked essential features and was so broad that it encompassed embodiments that would not work (e.g. devices without a void in the support layer for accommodating the wound to be treated). The patent was therefore insufficient for allowing the invention to be performed across the whole scope claimed. Moreover, the desired functions of the claimed layers given in the patent were broad and nebulous and did not give measurable or concrete advice to a person skilled in the art trying to reproduce the invention.

Reasons for the Decision

1. The invention

The invention relates to an offloading and reduced-pressure treatment device, which is for applying a reduced pressure to a tissue site on a plantar region of the foot. Such devices are typically used to apply suction to a wound, to promote its healing.

A device according to the invention is shown in Figure 1 of the patent as granted, reproduced below together with Figure 2.



The device comprises a plantar member (104) and a reduced-pressure interface (150). The plantar member is formed from an offloading manifold material comprising three layers visible in Figure 2. These are a support layer (128), a pressure-transmitting layer (134) and a first barrier layer (140). The reduced-pressure interface is coupled to the pressure-transmitting layer of the plantar member, to convey reduced pressure to the wound to be treated.

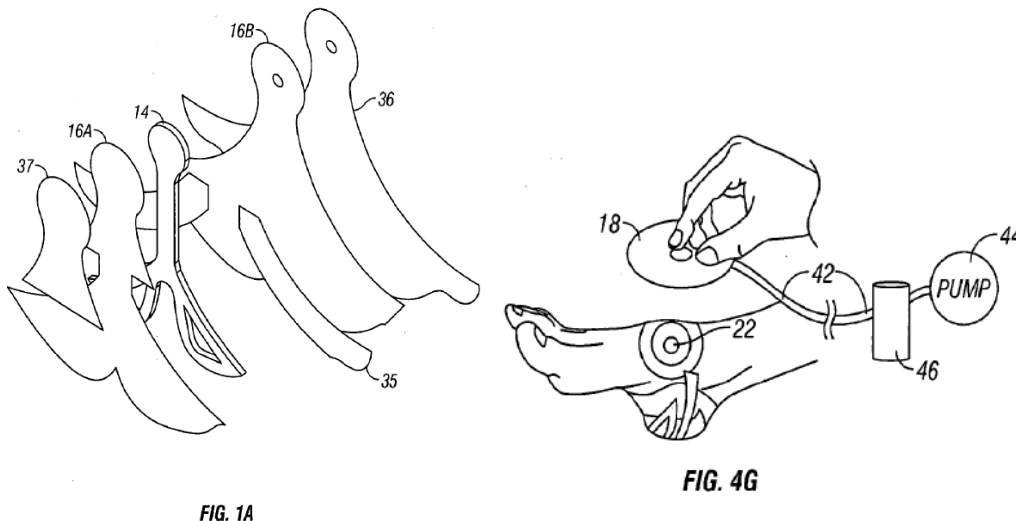
By permitting offloading of a wound on a plantar region of the foot, the claimed device may facilitate its healing with a reduced-pressure treatment.

2. Novelty

2.1 The opponent argued that each of E2 and E3 deprived the subject-matter of claim 1 of the patent as granted of novelty.

2.2 E2 discloses a device for treating chronic wounds on the heel of a human foot (Figures 1A and 4G, reproduced

below) by application of reduced pressure (paragraph [0002]).



The device comprises a plantar member in the form of an occlusive wrapping (depicted in an exploded view in Figure 1A), and a reduced-pressure interface (fluid communication port 18 described in paragraph [0024] and shown in Figure 4G). The occlusive wrapping is for placement under a part of the sole of a foot, therefore it qualifies as a plantar member within the meaning of claim 1 of the patent as granted. The occlusive wrapping comprises a pressure-transmitting layer (fluid manifold 14) and a barrier layer (outer layer 16B). There is no disclosure in E2 that inner layer 16A may provide any support to the plantar region of the foot. To the contrary, E2 states that in order to avoid adhesions, a contoured pad is provided as a wound contact screen (paragraph [0025]).

Nonetheless, the Opposition Division and the opponent considered inner layer 16A to be a support layer of an offloading manifold material within the meaning of claim 1. In their view any layer providing a support function, i.e. an increased resistance to deformation,

even if only small, would provide an offloading function and therefore would be a support layer of an offloading manifold material within the meaning of claim 1 of the patent as granted.

The assessment of novelty in view of E2 thus hinges on the interpretation of the terms "support layer" of an offloading manifold material in claim 1 of the patent as granted.

According to established case law, a claim must be interpreted by the person skilled in the art in a technically sensible manner, taking into account the disclosure of the patent as a whole ("Case Law of the Boards of Appeal", 9th edition 2019, II.A.6.1). At the same time, any term must be interpreted in context, which consists of the other terms employed in the claims as well as the description (T 1646/12, point 2.1 of the Reasons and, more generally, "Case Law of the Boards of Appeal", 9th edition 2019, II.A.6.3.3).

The technical context of the patent is that of providing reduced pressure to treat a wound. According to claim 1 of the patent as granted, the support layer is part of a plantar member. Hence, it has to provide support to the plantar region of the foot, which implies offloading of physical pressure, in accordance with paragraph [0015] of the patent. In turn, this requires a certain thickness of the support layer and a certain pressure which the support layer has to withstand before collapsing and transferring weight directly to the pressure-transmitting layer.

Although neither the claim nor the patent define a specific pressure level which the support layer has to withstand before collapsing, as the opponent remarked,

this pressure level is removed from around a plantar wound being treated (paragraph [0015] of the patent). Therefore, it must relate to the weight of a person.

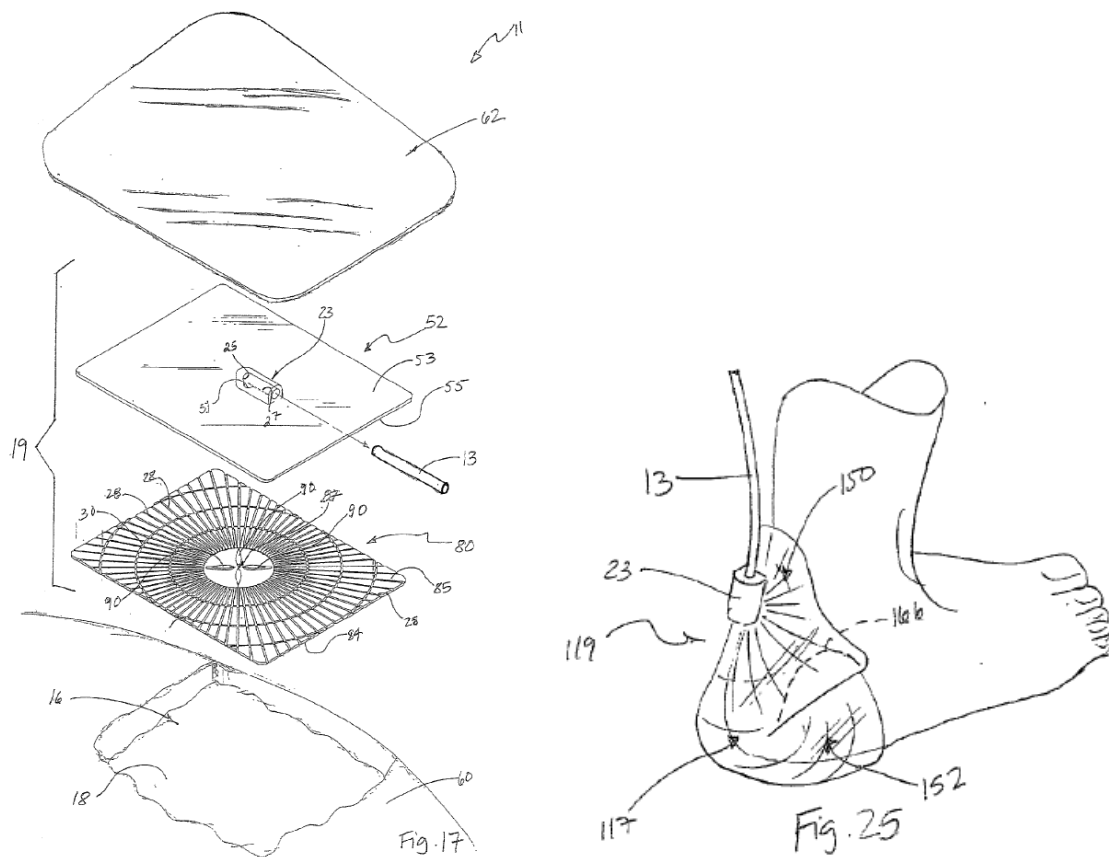
The person could be a child or an adult. The weight does not have to be the person's entire weight. Still, a flexible film of material which directly transfers force to a lower layer of material provides no offloading of pressure at all within the meaning of the claim and thus cannot be interpreted as a support layer falling within the scope of claim 1 of the patent as granted.

Paragraph [0017] of the patent, referred to by the opponent and the Opposition Division in the impugned decision, simply does not state that a thin coating could be equated to the support layer as claimed. It merely states that an open-cell foam can be "coated with a non-breathable material [e.g. vinyl material] that also provides some offloading strength".

Hence, inner layer 16A from E2, for which no supporting function is disclosed, cannot be regarded as a "support layer" within the meaning of the claim.

It follows that the subject-matter of claim 1 of the patent as granted is novel (Article 54(1) and (2) EPC) over E2.

2.3 E3 also discloses a device for treating chronic wounds by application of reduced pressure (paragraph [0002] and Figures 17 and 25 reproduced below).



The device comprises a member (19, 119) for use in a vacuum bandage, and a reduced-pressure interface (connector 23). In the embodiment in Figure 25, member 119 is for placement under a part of the sole of a foot. Hence, it qualifies as a plantar member within the meaning of claim 1 of the patent as granted. Member 119 comprises a pressure-transmitting layer and a barrier layer (described as a wound contacting layer and a cover, respectively, in paragraph [0101], with a configuration analogous to that of member 19 with wound contacting layer 80 and cover 52 in Figure 17).

The Opposition Division and the opponent considered that an integrally formed wound contacting element could constitute both the support layer and the pressure-transmitting layer as defined in claim 1 of

the patent as granted.

This was the case by virtue of the special definition in paragraph [0013] of the patent, which stated that the term "coupled" included "two or more components that are continuous with one another by virtue of each of the components being formed from the same piece of material". This interpretation was also supported by paragraph [0017], which expressly stated that an alternative embodiment comprised a single layer instead of a support layer and a pressure-transmitting layer.

The Board acknowledges that a patent document may be its own dictionary and the description and the drawings could give a special meaning to a term in a claim.

Still, the interpretation of a claim term cannot ignore the other terms employed in the claim. Indeed, the claims define the matter for which protection is sought (Article 84 EPC and Rule 43(1) EPC). Hence, the Board agrees with the proprietor that interpreting claims in the light of the description has limitations if this introduces a contradiction with the linguistic structure of the claim which imparts clear technical teaching to the skilled reader (see also "Case Law of the Boards of Appeal", 9th edition 2019, section II.A. 6.3.1, and decisions T 1018/02, point 3 of the Reasons, and T 1395/07, point 3.8 of the Reasons, cited in this section).

A similar position has been taken by national courts, for instance by the German Federal Court of Justice in its decision X ZR 16/09 (OLG Düsseldorf) and by the England and Wales Court of Appeal in the decision *Occlutech GmbH v AGA Medical Corporation* [2010] EWCA Civ 702.

The Board notes that claim 1 of the patent as granted defines three layers, each with its own specific function. Each of these layers comprises two surfaces. The layers are coupled to each other through the coupling between respective surfaces. Although the description of the patent (paragraph [0013]) assigns a broad meaning to the term "coupled", which should encompass "two or more components that are continuous with one another by virtue of each of the components being formed from the same piece of material", the explicit definition in the claim that the coupling is between the respective layer surfaces, i.e. the outside of the respective layers, provides a limit to this general definition of the term "coupled". In other words claim 1 of the patent as granted requires three distinct layers, which can be individually recognised and can individually perform their claimed functions. This is in conformity with the structure of the embodiment of the patent depicted in Figures 2, 5, 6 and 10, which falls within the scope of claim 1.

The opponent's argument that the claim could be interpreted such that a surface of the pressure-transmitting layer and a surface of the support layer could be identified at a boundary between the two layers when these layers are integrally formed is not convincing. This interpretation would be based on an arbitrary definition of two internal surfaces in a continuous material, which would render the relevant claim wording technically meaningless. With regard to the alternative embodiment mentioned in paragraph [0017], which is expressly stated as comprising a single layer instead of a support layer and a pressure-transmitting layer, it does not fall within the scope of claim 1 of the patent as granted, which requires

both of these layers.

Hence, since claim 1 requires the treatment device to have three individual layers, the subject-matter of claim 1 of the patent as granted is novel (Article 54(1) and (2) EPC) over E3 by virtue of the defined support layer of the offloading manifold material.

2.4 It follows that the opponent's objections based on the ground for opposition of lack of novelty under Article 100(a) EPC do not prejudice the maintenance of the patent as granted.

3. Inventive step

The opponent argued that the subject-matter of claim 1 of the patent as granted was not inventive when starting from one of E2, E3, E4 and E10.

3.1 Starting from E2, E3 or E10, these documents do not disclose a support layer of an offloading manifold material as defined in the claim. In particular, E10 discloses a wound closure dressing with a structure similar to that of E3. The wound closure dressing comprises two layers in the form of a foam dressing making up a reduced-pressure-transmitting layer and an adhesive drape making up a barrier layer.

The support layer as defined in the claim provides a pressure-offloading effect which may be used to avoid direct contact between the wound and a surface of the plantar member (Figure 5 of the patent). This prevents adhesions, which improves the effectiveness of the treatment.

The Board therefore shares the proprietor's view that the objective technical problem solved by the distinguishing feature is to improve the treatment of a wound on a plantar region of a foot. In its formulation of the problem, the opponent merely paraphrased the effect of the distinguishing feature. This cannot be accepted as it provides a pointer to the solution.

There is no teaching in the available prior art to provide a support layer as claimed in the devices of E2, E3 or E10 in order to address the objective technical problem.

Moreover, E2 teaches an occlusive wrapping for being placed over the heel of the foot. The importance of having a wrapping that maintains a negative pressure over a wound which exists in a highly contoured part of the body is emphasised (paragraph [0005]). This implies high flexibility of the wrapping, which has to closely match the shape of that part of the body. In order to prevent adhesions E2 discloses the additional use of a contoured pad 26 (paragraph [0025]).

Providing a support layer in E2 is neither useful for preventing adhesions nor desirable, as its mere presence would, at least to a certain degree, affect the flexibility of the occlusive wrapping.

Therefore, the person skilled in the art would not provide a support layer as claimed in the device of E2, on the basis of E2 alone or in combination with E6 or E8, even though E6 and E8 disclose such a layer.

The same applies when starting from E3, which discusses advantages related to the flexibility of the member for use in the vacuum bandage (paragraphs [0004]

and [0008]). In order to prevent adhesions E3 discloses a system of channels in the wound contacting layer (Figures 17 and 24).

As regards E10, this document discloses the insertion of a porous foam dressing directly within the wound (column 8, lines 20 to 33). In addition to the pressure-offloading effect of the porous foam dressing as such, a foot compression wrap connected to a source of positive pressure is provided. Therefore, there is no incentive to provide a further support layer as claimed.

The opponent's reference to E11 and E12 does not lead to another result. Neither the sheet of elastomeric material (38) disclosed in E11 nor the membrane (219) disclosed in E12 is a support layer of an offloading manifold material within the meaning of claim 1 of the patent as granted.

It follows that the subject-matter of claim 1 of the patent as granted is inventive (Article 56 EPC) when starting from E2, E3 or E10.

- 3.2 Starting from E4, the Board notes that this document relates to footwear having orthopaedic soles providing pressure relief areas for the feet (column 1, lines 16 and 17). It is not concerned with a device for treatment of a wound by providing reduced pressure within the meaning of claim 1 of the patent as granted. The Board concludes that this document is not a promising starting point towards the claimed invention, because its very purpose would have to be changed. This change would only be made with hindsight.

It follows that the subject-matter of claim 1 of the

patent as granted is inventive (Article 56 EPC) when starting from E4.

3.3 Hence, the opponent's objections based on the ground for opposition of lack of inventive step under Article 100(a) EPC do not prejudice the maintenance of the patent as granted.

4. Sufficiency of disclosure

The opponent argued that the subject-matter of claim 1 of the patent as granted was so broad that it encompassed embodiments that would not work.

However, the mere fact that the claim wording may cover non-working embodiments does not mean that the claimed invention is insufficiently disclosed. A patent specification is directed to the person skilled in the art, who would exclude such non-working embodiments.

The opponent did not specify which of the claimed features could not be carried out by the person skilled in the art on the basis of the disclosure of the patent, and why. The patent discloses in detail, for instance in paragraphs [0012] to [0016], how to implement an offloading and reduced-pressure treatment device with the features of claim 1.

The lack of essential features alleged by the opponent may relate to the clarity of the claim, but not to sufficiency of disclosure, which has to be assessed on the basis of the patent as a whole.

In conclusion, the subject-matter of claim 1 of the patent as granted is sufficiently disclosed.

Hence, the opponent's objection based on the ground for opposition of insufficiency of disclosure under Article 100(b) EPC does not prejudice the maintenance of the patent as granted.

5. The patent is to be maintained as granted under Article 101(2) EPC since none of the opponent's objections prejudices its maintenance.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The patent is maintained as granted.

The Registrar:

The Chairman:



D. Hampe

M. Alvazzi Delfrate

Decision electronically authenticated