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Datasheet for the decision of 17 January 2019

Case Number: T 1396/13 - 3.2.02

Application Number: 06785522.1

Publication Number: 1896115

IPC: A61M37/00

Language of the proceedings: EN

Title of invention:
MICRONEEDLE CARTRIDGE ASSEMBLY

Patent Proprietor:
3M Innovative Properties Company

Opponent:
Koch, Jens

Headword:

Relevant legal provisions:
EPC Art. 123(2), 54, 56
RPBA Art. 13(1)

Keyword:

Added subject-matter - new auxiliary request II (no)
Novelty - main request (no)
Inventive step - auxiliary request I (no) - new auxiliary request II (yes)
Late-filed new auxiliary request II - admitted (yes)

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

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Case Number: T 1396/13 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 17 January 2019

Appellant: (Patent Proprietor)	3M Innovative Properties Company 3M Center P.O.Box 33427 St. Paul, MN 55133-3427 (US)
Representative:	Vossius & Partner Patentanwälte Rechtsanwälte mbB Siebertstrasse 3 81675 München (DE)
Respondent: (Opponent)	Koch, Jens Leopoldstrasse 4 80802 Munchen (DE)
Representative:	Grünecker Patent- und Rechtsanwälte PartG mbB Leopoldstraße 4 80802 München (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 5 April 2013 concerning maintenance of the European Patent No. 1896115 in amended form.**

Composition of the Board:

Chairman E. Dufrasne
Members: S. Böttcher
D. Ceccarelli

Summary of Facts and Submissions

I. The patent proprietor lodged an appeal against the interlocutory decision of the Opposition Division, dispatched on 5 April 2013, that, account being taken of the amendments according to Auxiliary Request III made by the patent proprietor during the opposition proceedings, European patent No. EP 1 896 115 and the invention to which it related met the requirements of the EPC.

II. Opposition was filed against the patent as a whole based on the grounds for opposition of lack of novelty and lack of inventive step pursuant to Article 100(a) EPC.

III. Notice of appeal was filed by the appellant/proprietor on 13 June 2013. The appeal fee was paid on the same day. The statement setting out the grounds of appeal was received on 13 August 2013.

IV. The parties were summoned to oral proceedings by letter dated 15 October 2018.

V. By letter dated 26 November 2018 the respondent/ opponent announced that it would not be represented at the oral proceedings.

VI. Oral proceedings took place on 17 January 2019.

The appellant requested that the decision under appeal be set aside and that the patent be maintained as granted or, in the alternative, on the basis of one of auxiliary request I, filed with letter dated 13 August 2013, and new auxiliary request II, filed during the

oral proceedings. All other requests were withdrawn.

The respondent had requested in writing that the appeal be dismissed.

VII. The following documents are referred to in this decision:

D1: WO-A-03/059431
D4: DE-A-36 42 931
D6: DE 38 44 247
D7: DE 199 16 523

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

"A microneedle array cartridge comprising:

a web of material having a top face and an opposite bottom face;
an adhesive disposed on the bottom face of the web of material;
a microneedle array disposed on the bottom face of the web of material; and
a container disposed relative to the bottom face of the web of material having a perimeter portion and a central portion for covering at least part of the microneedle array, wherein at least part of the perimeter portion contacts the adhesive and the central portion does not contact the adhesive, and wherein the perimeter portion and the central portion are integrally formed."

IX. Claim 1 of auxiliary request I is based on claim 1 as granted and includes the following additional features:

"wherein a first region of the perimeter portion

contacts the adhesive,
wherein a second region of the perimeter portion does not contact the adhesive, and wherein the central portion of the container has a base and at least one sidewall."

X. Claim 1 of new auxiliary request II corresponds to claim 1 of auxiliary request III on which the impugned decision was based and reads as follows:

"A microneedle array cartridge comprising:
a web of material having a top face and an opposite bottom face;
an adhesive disposed on the bottom face of the web of material;
a microneedle array disposed on the bottom face of the web of material; and
a container disposed relative to the bottom face of the web of material having a perimeter portion and a central portion for covering at least part of the microneedle array, wherein at least part of the perimeter portion contacts the adhesive and the central portion does not contact the adhesive, and wherein the perimeter portion and the central portion are integrally formed,
wherein the perimeter portion of the container defines a pair of cutout regions where the perimeter portion does not extend as far as the web perimeter."

XI. Claim 16 of new auxiliary request II corresponds to claim 19 of auxiliary request I and reads as follows:

"A microneedle array cartridge comprising:
a web of material disposed substantially in a first plane, the web of material having a top face and an opposite bottom face;

an adhesive disposed on the bottom face of the web of material;
a microneedle array disposed on the bottom face of the web of material; and
a container disposed relative to the bottom face of the web of material having a perimeter portion and a central portion having a base and at least one sidewall for covering at least part of the microneedle array, wherein a first region of the perimeter portion is disposed substantially in a second plane that is generally parallel to the first plane, and wherein a second region of the perimeter portion is generally not disposed in the second plane."

XII. The appellant's arguments relevant for the present decision can be summarised as follows:

Main request - novelty

The microneedle device of D1 (figure 14 and page 15 line 29 to page 16, line 16) could not be considered to be a cartridge. D1 did not disclose the use of the device in an applicator device. Rather, the device of D1 was to be applied by manual pressure.

Moreover, as D1 disclosed a cap (790) having a formed shape, it could not be concluded that the cap was rigid to form a cartridge. The cap was rather used for packing the device, and D1 disclosed that for this purpose it could be formed of flexible laminates instead of having a formed shape. Hence, D1 did not disclose a rigid cartridge.

Auxiliary request I - inventive step

Starting from D1 as the closest prior art, the distinguishing feature was that a second region of the perimeter portion did not contact the adhesive. As shown in Figures 1 to 3 and explained in paragraphs [0022], [0026] and [0029] of the patent, due to the second region being spaced from the adhesive, a gap (46) was created. The purpose of this gap was to facilitate the sliding of the retainer members (60) of the applicator between the web and the container. The problem to be solved, therefore, was to provide improved loading of the array to the applicator.

D1 disclosed neither a microneedle cartridge nor an applicator. The cap (790) had to be taken off manually before the microneedle array could be applied to the patient.

The skilled person would not have turned to D4 since D4 did not disclose an applicator either. D4 did not even relate to a microneedle array but to a transdermal plaster.

Furthermore, D4 disclosed an adhesive-free tab (7) that facilitated removal of the protective layer. However, the provision of such a tab in the device of D1 would hinder the introduction of the device into an applicator.

A combination of the teachings of D1 and D4 would not lead to an embodiment according to Figure 2 of the present patent in which the second region could contact the adhesive but did not because of the gap (46). The skilled person would have understood the wording "a second region of the perimeter portion does not contact the adhesive" to mean that a space or gap had to be provided. An adhesive-free portion or tab was not meant

by claim 1.

New auxiliary request II - admissibility

New auxiliary request II was based on auxiliary request I from which claim 1 and two dependent claims had been deleted. Hence all the claims of the new auxiliary request II had already been present in the appeal procedure. Therefore, the respondent could not have been taken by surprise, and the request should be admitted.

New auxiliary request II - claim 16 - added subject-matter

The introduction of the first part of claim 14 did not constitute an intermediate generalisation since the feature of the container having a low profile was clearly disclosed as an optional feature in the description of the patent (column 7, lines 2 to 6).

New auxiliary request II - claim 16 - inventive step

The feature that the second region was not disposed in the second plane solved two problems, namely, to facilitate the insertion of the microneedle array into the applicator and the simultaneous removal of the container. Since this feature was not known from the prior art on file, the subject-matter of claim 16 involved an inventive step.

XIII. The respondent's arguments relevant for the present decision can be summarised as follows:

Main request - novelty

The term "cartridge" did not imply any statement on the rigidity properties of the container. Claim 1 only referred to the form of the container and not to its material properties.

Moreover, the expression "formed shape" used in D1 required that the cap (790) be rigid.

Auxiliary request I - inventive step

Patches having adhesive-free gripping tabs to facilitate the removal of a cover layer were known in the prior art, as for instance is shown in Figure 10 of D4. The provision of a second region which does not contact the adhesive was therefore obvious to facilitate the separation of the container from the patch.

New Auxiliary request II - claim 16 - added subject-matter

Claim 16 included the first part of original claim 14, namely, that "the central portion of the container has a base and at least one sidewall". The omission of the second part of claim 14, i.e. the feature that "the at least one sidewall has a low profile relative to the microneedle array" resulted in an unallowable intermediate generalisation. Since both features were inextricably linked by an "and" conjunction and because the second feature presupposed the first feature, the first feature could not be isolated from the combination of features.

New Auxiliary Request II - claim 16 - inventive step

There was no synergistic effect between the microneedle

array disposed on the web of material and the "second region" not disposed in the second plane. The provision of this second region solved a simple unpacking problem. Hence, although D4, D6 and D7 related to dermal patches without microneedles, the skilled person would have applied the solution offered in this document to a microneedle patch without any inventive activity.

Reasons for the Decision

1. The appeal is admissible.

2. The invention relates to microneedle array cartridges comprising a web of material. An adhesive and a microneedle array are disposed on the bottom face of the web of material. The microneedle array is covered by a container having a central portion and a perimeter portion. At least part of the perimeter portion contacts the adhesive while the central portion does not contact the adhesive.

The microneedles are capable of piercing the stratum corneum to facilitate the transdermal delivery of therapeutic agents or the sampling of fluids through the skin.

The container helps to protect the microneedle array from contamination and damage prior to deployment.

To apply the patch to the patient, the cartridge is loaded into an applicator device, and the container is separated from the patch to uncover the microneedle array which is then accelerated by the applicator device to pierce the needles into the skin.

To facilitate removal of the container, the perimeter portion may define a pair of cutout regions (34) (Figure 5). Alternatively, a region of the perimeter portion may be spaced from the adhesive on the web of material to form a gap (46) (Figure 2).

3. *Main request - novelty*

3.1 D1 discloses a microneedle device (Figure 14 and page 15, line 29, to page 16, line 11) comprising a web of material (backing 760), an adhesive disposed on a bottom face of the web of material (page 16, lines 4 to 8), a microneedle array (substrate 720 and microneedles 730), and a container (cap 790) with a central portion for covering the microneedle array and a perimeter portion. As can be seen from Figure 14, the central portion does not contact the adhesive which forms the seal between the perimeter portion and the backing. The perimeter portion and the central portion are integrally formed. To apply the device to a patient, the cap is removed manually before the device is placed on the skin.

Hence, the device of D1 includes all the features of claim 1, apart from it not being named a cartridge.

3.2 The appellant argued that the term cartridge was used for a container which interacts with another device. Since in D1 no such interaction was disclosed, the device could not be considered a cartridge.

However, even if it is not mentioned in D1 that the microneedle device can be mounted on an applicator device, there are no structural differences between the microneedle device of D1 and the claimed cartridge which would preclude the device of D1 from being used

as a cartridge which can be loaded on an applicator device.

3.3 The appellant further brought forward that the device of D1 did not comprise a rigid container as it would be necessary to mount the microneedle array in an applicator.

The Board does not concur with the appellant that the term "cartridge" implies a certain rigidity of the container. It might be true that the applicator described in the present patent requires a certain rigidity of the container because of the way the microneedle patch is loaded on it. However, other types of applicator devices may not require a specifically rigid container. Since the applicator is not defined in the claim, it cannot be concluded that the container must be specifically rigid for the microneedle device to be called a cartridge

Irrespective of this, the cap (790) of D1 is specified as having a formed shape (page 16, lines 9 to 11), which gives it a certain degree of rigidity. The fact that flexible laminates are mentioned as an alternative for the cap (790) in D1, as pointed out by the appellant, does not contradict this finding.

3.4 Consequently, the subject-matter of claim 1 of the patent as granted lacks novelty in view of D1.

4. Auxiliary request I - inventive step

4.1 Starting from D1 as the closest prior art, the subject-matter of claim 1 differs from the microneedle array cartridge of Figure 14 in that a second portion of the

perimeter portion does not contact the adhesive.

4.2 The problem to be solved by this feature may be regarded as to facilitate the separation of the container from the patch for applying the patch to the patient.

4.3 However, the provision of a second region of the perimeter portion which does not contact the adhesive to facilitate separating the container from the patch does not involve an inventive step. D4 discloses a peel-off tab that can be regarded as such a second portion (Figure 14 and column 5, lines 5 to 6) for the same purpose. It would be obvious for the skilled person to have provided such a peel-off tab on the microneedle device of D1.

4.4 The Board does not agree with the appellant that the problem to be solved is to provide improved loading of the array to the applicator. As described in paragraph [0029] of the present patent, during the mounting of the array to the applicator, the ends of the retainer members (60) are positioned in the gap (46) formed between the web of material and the perimeter lip. However, claim 1 defines no such gap. It merely describes a portion which does not contact the adhesive. Hence, "improved loading" cannot be the problem to be solved by the distinguishing feature.

4.5 Furthermore, the Board does not accept the appellant's view that the skilled person would have understood the wording "a second region of the perimeter portion does not contact the adhesive" to mean that a gap had to be provided. Although the wording might be understood as meaning that there is adhesive on the second region but that the perimeter portion does not contact it, it

could just as well mean that there is no adhesive which can be contacted, as shown in D4.

4.6 The appellant further stated that the skilled person would not have turned to D4 since D4 disclosed neither an applicator nor a microneedle array.

However, in consideration of the problem to be solved, namely, to facilitate the removal of a cover of a patch, the skilled person would very well have used the teaching of D4 since it relates to the same problem.

4.7 Furthermore, the Board does not concur with the appellant that the provision of a tab, like in D4, would have hindered the introduction of the device into an applicator.

Actually, the present patent also discloses a handling tab which may be affixed to the container to make it more easily graspable (column 6, lines 49 to 53). Thus, the patch can obviously be inserted into the applicator in spite of this tab.

4.8 Consequently, the subject-matter of claim 1 of auxiliary request I lacks an inventive step (Article 56 EPC).

5. *New auxiliary request II - admissibility*

5.1 New auxiliary request II entails the deletion of claim 1 of auxiliary request I.

5.2 The admissibility of this request was not objected to by the respondent.

5.3 The request could have been filed with the statement of grounds of appeal. However, the amendments made were restricted to the deletion of claims and therefore do not unnecessarily delay the proceedings.

5.4 Claims 1 to 15 and 17 to 19 of new auxiliary request II correspond to claims 1 to 15 and 16 to 18 of auxiliary request III on which the impugned decision was based.

The remaining independent claim 16 of new auxiliary request II had been in the appeal proceedings from the very beginning, e.g. as claim 19 in auxiliary request I.

5.5 Consequently, although filed at a very late stage (during the oral proceedings), new auxiliary request II is admitted into the proceedings.

6. *New auxiliary request II - claim 16 - added subject-matter*

6.1 Claim 16 is based on claim 20 as originally filed and further specifies that the central portion of the container has a base and at least one sidewall. This latter feature finds support in the first part of claim 14 as originally filed.

6.2 The respondent had raised an objection as to added subject-matter (Article 123(2) EPC) against claim 19 of auxiliary request I, which corresponds to claim 16 of the new auxiliary request II.

6.3 Contrary to the respondent, the Board does not consider the omission of the second part of claim 14 ("and wherein the at least one sidewall has a low profile relative to the microneedle array") to result in an

unallowable intermediate generalisation.

Page 8, lines 7 to 9 of the original description states that "the container can have a relatively low profile". Hence, the second part of claim 14 is in the description as an optional feature.

It follows that the feature "the central portion of the container has a base and at least one sidewall" is not inextricably linked with the feature "and wherein the at least one sidewall has a low profile relative to the microneedle array".

6.4 Hence, the amendments made to claim 16 of the new auxiliary request II meet the requirements of Article 123(2) EPC.

7. *New auxiliary request II - inventive step*

7.1 Claim 1

As mentioned above, claim 1 of new auxiliary request II corresponds to claim 1 of the auxiliary request III on which the impugned decision was based. Since the proprietor is the sole appellant, claim 1 may not be objected to (prohibition of *reformatio in peius*). In particular, it may not be challenged whether the subject-matter of claim 1 involves an inventive step.

The respondent did not raise any objections.

7.2 Claim 16

7.2.1 D1 is considered to represent the closest prior art for the subject-matter of claim 16. D1 discloses a microneedle array cartridge comprising:

a web of material (760) disposed substantially in a first plane, the web of material having a top face and an opposite bottom face;
an adhesive disposed on the bottom face of the web of material;
a microneedle array (720, 730) disposed on the bottom face of the web of material; and
a container (790) disposed relative to the bottom face of the web of material having a perimeter portion and a central portion for covering at least part of the microneedle array (720, 730), wherein a first region of the perimeter portion is disposed substantially in a second plane that is generally parallel to the first plane.

7.2.2 Hence, the following feature of claim 16 is not disclosed in D1:

a second region of the perimeter portion is generally not disposed in the second plane.

7.2.3 Due to the perimeter portion having a region which is not disposed in the second plane, a gap or slight separation is created between the bottom face of the web of material and the perimeter portion of the container. During insertion of the patch into the applicator, the retainer members of the applicator are positioned in the gap. Upon sliding the cartridge further along the retainer members, the container is simultaneously separated from the web of material.

7.2.4 The objective technical problem to be solved by the distinguishing feature is therefore to facilitate the insertion of the cartridge into the applicator and the simultaneous removal of the container.

7.2.5 Hence, contrary to the respondent's assertions, the feature "the second region being not disposed in the second plane" does not merely solve an unpacking problem. It also improves the handling of the microneedle array in connection with the applicator.

7.2.6 None of the cited prior art documents disclose the distinguishing feature for solving the above-mentioned technical problem. Hence, even if the skilled person would have considered the teaching of D4, D6 or D7, as presumed by the respondent, they would not have provided the microneedle patch with a second region not disposed in the second plane.

7.2.7 Consequently, the subject-matter of claim 16 of the new auxiliary request II involves an inventive step.

7.3 The respondent did not raise any other objections to the claims of the new auxiliary request II, and the Board does not have any either.

7.4 The description was adapted to the amended claims.

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 19 of new auxiliary request II, filed during the oral proceedings;

   - description columns 1 and 2, page 2a, and columns 5 to 13 as filed on 6 March 2013, and columns 3 and 4 as filed during the oral proceedings; and

   - figures 1 to 16 of the patent as granted.

The Registrar: The Chairman:

D. Hampe E. Dufrasne

Decision electronically authenticated