Internal distribution code:

(A) [-] Publication in OJ
(B) [-] To Chairmen and Members
(C) [-] To Chairmen
(D) [X] No distribution

Datasheet for the decision of 12 September 2022

Case Number: T 0431/18 - 3.2.02

Application Number: 09157468.1

Publication Number: 2130560

IPC: A61M5/158, A61M5/142

Language of the proceedings: EN

Title of invention:
device for administration

Patent Proprietor:
Unomedical A/S

Opponent:
Roche Diagnostics GmbH

Headword:

Relevant legal provisions:
EPC Art. 54
RPBA Art. 12(4)
RPBA 2020 Art. 13(1), 13(2)

Keyword:

Late-filed facts - objection filed after reply to the statement of grounds - admitted (yes)
Late-filed requests - submitted with the statement of grounds of appeal - admitted (yes)
Amendment to appeal case - amendment gives rise to new objections (yes) - taken into account (no)
Request submitted during oral proceedings - exceptional circumstances (no) - taken into account (no)
Novelty - (no)

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

Boards of Appeal

Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 0431/18 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 12 September 2022

Appellant: (Patent Proprietor)	Unomedical A/S Birkerød Kongevej 2 3460 Birkerød (DK)
Representative:	D Young & Co LLP 120 Holborn London EC1N 2DY (GB)
Appellant: (Opponent)	Roche Diagnostics GmbH Sandhoferstr. 116 68305 Mannheim (DE)
Representative:	Peterreins Schley Patent- und Rechtsanwälte PartG mbB Hermann-Sack-Strasse 3 80331 München (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 15 January 2018 concerning the maintenance of European Patent No. 2130560 in amended form**

Composition of the Board:

Chairman	M. Alvazzi Delfrate
Members:	D. Ceccarelli
	N. Obrovski

Summary of Facts and Submissions

I. The patent proprietor and the opponent appealed against the Opposition Division's decision that, account being taken of the amendments made by the patent proprietor during the opposition proceedings according to auxiliary request 4, the European patent and the invention to which it relates met the requirements of the EPC.

II. The Board summoned the parties to oral proceedings and provided a preliminary opinion on the case.

III. Oral proceedings took place on 12 September 2022.

The appellant/opponent ("the opponent") requested that the decision under appeal be set aside and that the patent be revoked.

The appellant/patent proprietor ("the proprietor") requested that the decision under appeal be set aside and that a patent be granted on the basis of one of:

- the second and third auxiliary requests filed by letter dated 25 May 2018,
- auxiliary request 4 filed during oral proceedings before the Opposition Division on 12 December 2017,
- the ninth and tenth auxiliary requests filed by letter dated 5 April 2022, or
- the eleventh auxiliary request filed during oral proceedings before the Board on 12 September 2022.

IV. The following document is relevant to this decision:

D2: WO 2006/032692 A1

V. Claim 1 of the **second auxiliary request** reads as follows:

"A device for delivering fluid, comprising an injection part and a fluid delivery part (3, 4), wherein the fluid delivery part comprises a reservoir (4), transfer means, and a housing (3), and wherein the injection part comprises
a base plate (10) comprising means for fastening (11) the fluid delivery part to the base plate in such a way that the fluid delivery part (3, 4) can be attached to and separated from the base plate (10) during use, the means for fastening (11) extending from the distal side of the base plate; and
means (21) for fixation of the base plate (10) to the skin of a patient
characterized in that the injection part comprises a cannula part which is a two-part unit comprising a first cannula part (1a) and a second cannula part (1b) wherein the first cannula part (1a) is fastened unreleasably to the base plate (10) and the second cannula part (1b) is configured to be inserted into the position defined by the first cannula part (1a) and attached to the base plate (10) after the base plate (10) has been positioned on the skin of the patient, the cannula part (1b) comprising a body which during use provides a through-going opening leading liquid to a soft cannula (9) extending past the proximal side of the base plate (10), and the base plate comprising a surface corresponding to an inserter device for the cannula part (1b),
wherein a flexible part is arranged in an area between

a subcutaneously positioned section of the soft cannula (9) and the fluid delivery part (3, 4)."

Claim 1 of the **third auxiliary request** reads as follows:

"A device for delivering fluid, comprising an injection part and a fluid delivery part (3, 4), wherein the fluid delivery part comprises a reservoir (4), transfer means, and a housing (3), and wherein the injection part comprises
a base plate (10) comprising means for fastening (11) the fluid delivery part to the base plate in such a way that the fluid delivery part (3, 4) can be attached to and separated from the base plate (10) during use, the means for fastening (11) extending from the distal side of the base plate; and
means (21) for fixation of the base plate (10) to the skin of a patient
characterized in that the injection part comprises a cannula part which is a two-part unit comprising a first cannula part (1a) and a second cannula part (1b) wherein the first cannula part (1a) is fastened unreleasably to the base plate (10) and the second cannula part (1b) is configured to be inserted into the position defined by the first cannula part (1a) and attached to attached to *[sic]* the base plate (10) after the base plate (10) has been positioned on the skin of the patient, the cannula part (1b) comprising a body which during use provides a through-going opening leading liquid to a soft cannula (9) extending past the proximal side of the base plate (10), and the base plate comprising a surface corresponding to an inserter device for the cannula part (1b),
wherein a flexible part is arranged in an area between a subcutaneously positioned section of the soft cannula

(9) and the fluid delivery part (3, 4), and wherein the flexible part reduces the transferal of actions from the fluid delivery part to the subcutaneously positioned section of the cannula (9)."

Claim 1 of **auxiliary request 4** reads as follows:

"A device for delivering fluid, comprising an injection part and a fluid delivery part (3, 4), wherein the fluid delivery part comprises a reservoir (4), a pump, and a housing (3), and wherein the injection part comprises:
a base plate (10) comprising means for fastening (11) the fluid delivery part to the base plate in such a way that the fluid delivery part (3, 4) can be attached to and separated from the base plate (10) during use, the means for fastening (11) extending from the distal side of the base plate; and
means (21) for fixation of the base plate (10) to the skin of a patient,
wherein
a flexible part is integrated in the base plate and arranged in an area between a subcutaneously positioned section of a cannula (9) and the fluid delivery part (3, 4),
wherein the flexible part reduces the transferal of actions from the fluid delivery part to the subcutaneously positioned section of the cannula (9),
the injection part is constructed of at least 2 separable parts where a first part is unreleasably connected to the base plate and
the injection part comprises a second part being a cannula part (1b) comprising the cannula, configured to be placed in the first part, the first part being provided with locking means for locking the cannula in a desired position, and thus the cannula part (1b) is

inserted and attached to the base plate (10) after the base plate (10) has been positioned on the skin of the patient,
the cannula part (1b) also comprising a body which during use provides a through-going opening leading liquid to the cannula, being a soft cannula (9) extending past the proximal side of the base plate (10), and
the base plate comprising a surface corresponding to an inserter device for the cannula part (1b)."

Claim 1 of the **ninth auxiliary request** reads as follows:

"A device for delivering fluid, comprising an injection part and a fluid delivery part (3, 4), wherein the fluid delivery part comprises a reservoir (4), transfer means, and a housing (3), and wherein the injection part comprises
a base plate (10) comprising means for fastening (11) the fluid delivery part to the base plate in such a way that the fluid delivery part (3, 4) can be attached to and separated from the base plate (10) during use, the means for fastening (11) extending from the distal side of the base plate; and
means (21) for fixation of the base plate (10) to the skin of a patient
characterized in that the injection part comprises a cannula part which is a two-part unit comprising a first cannula part (1a) and a second cannula part (1b) wherein the first cannula part (1a) is fastened unreleasably to the base plate (10) and the second cannula part (1b) is configured to be inserted into the position defined by the first cannula part (1a) and attached to the base plate (10) after the base plate (10) has been positioned on the skin of the patient,

the cannula part (1b) comprising a body which during use provides a through-going opening leading liquid to a soft cannula (9) extending past the proximal side of the base plate (10), and the base plate comprising a surface corresponding to an inserter device for the cannula part (1b),
wherein a flexible part is arranged in an area between a subcutaneously positioned section of the soft cannula (9) and the fluid delivery part (3, 4),
wherein the flexible part is constructed of an area with reduced material dimensions, or the flexible part is constructed of an area made of a material which by its form has an ability for extension and compression wherein the material is pleated or folded or corrugated."

Claim 1 of the **tenth auxiliary request** reads as follows:

"A device for delivering fluid, comprising an injection part and a fluid delivery part (3, 4), wherein the fluid delivery part comprises a reservoir (4), a pump, and a housing (3), and wherein the injection part comprises:
a base plate (10) comprising means for fastening (11) the fluid delivery part to the base plate in such a way that the fluid delivery part (3, 4) can be attached to and separated from the base plate (10) during use, the means for fastening (11) extending from the distal side of the base plate; and
means (21) for fixation of the base plate (10) to the skin of a patient,
wherein
a flexible part is integrated in the base plate and arranged in an area between a subcutaneously positioned section of a cannula (9) and the fluid delivery part

(3, 4), wherein the flexible part reduces the transferal of actions from the fluid delivery part to the subcutaneously positioned section of the cannula (9), wherein the flexible part is constructed of an area with reduced material dimensions, or the flexible part is constructed of an area made of a material which by its form has an ability for extension and compression wherein the material is pleated or folded or corrugated,
the injection part is constructed of at least 2 separable parts where a first part is unreleasably connected to the base plate and
the injection part comprises a second part being a cannula part (1b) comprising the cannula, configured to be placed in the first part, the first part being provided with locking means for locking the cannula in a desired position, and thus the cannula part (1b) is inserted and attached to the base plate (10) after the base plate (10) has been positioned on the skin of the patient,
the cannula part (1b) also comprising a body which during use provides a through-going opening leading liquid to the cannula, being a soft cannula (9) extending past the proximal side of the base plate (10), and
the base plate comprising a surface corresponding to an inserter device for the cannula part (1b)."

Claim 1 of the **eleventh auxiliary request** reads as follows:

"A device for delivering fluid, comprising an injection part and a fluid delivery part (3, 4), wherein the fluid delivery part comprises a reservoir (4), transfer means, and a housing (3), and wherein the injection part comprises

a base plate (10) comprising means for fastening (11) the fluid delivery part to the base plate in such a way that the fluid delivery part (3, 4) can be attached to and separated from the base plate (10) during use, the means for fastening (11) extending from the distal side of the base plate; and
means (21) for fixation of the base plate (10) to the skin of a patient
characterized in that the injection part comprises a cannula part which is a two-part unit comprising a first cannula part (1a) and a second cannula part (1b) wherein the first cannula part (1a) is fastened unreleasably to the base plate (10) and the second cannula part (1b) is configured to be inserted into the position defined by the first cannula part (1a) and attached to the base plate (10) after the base plate (10) has been positioned on the skin of the patient, the cannula part (1b) comprising a body which during use provides a through-going opening leading liquid to a soft cannula (9) extending past the proximal side of the base plate (10), and the base plate comprising a surface corresponding to an inserter device for the cannula part (1b),
wherein a flexible part is arranged in an area between a subcutaneously positioned section of the soft cannula (9) and the fluid delivery part (3, 4),
wherein the flexible part is constructed of openings or cuts provided in a material."

VI. The proprietor's arguments, where relevant to this decision, can be summarised as follows:

Admittance of novelty objections based on D2 and of the second, third and ninth to eleventh auxiliary requests

On appeal, the opponent had raised novelty objections

in view of D2 only after its reply to the proprietor's statement of grounds. These objections should have been raised during the proceedings at first instance or, at the very least, with the opponent's statement of grounds of appeal or reply. As was apparent from point 4.5.1 of the minutes of the oral proceedings before the Opposition Division, the opponent had explicitly stated that it did not have any novelty objections in view of D2 against auxiliary request 4. To file such objections at a late stage of the appeal proceedings was not conducive to procedural economy and put the patentee at a significant disadvantage by it having to consider new amendments. This was also contrary to the fundamental principle of *inter partes* proceedings before the EPO that all parties should be subject to fair and equal treatment. Hence, the novelty objections based on D2 were not to be admitted.

The second and third auxiliary requests had been submitted with the statement of grounds of appeal and comprised technical features already present in requests submitted in the first-instance proceedings. They were to be admitted into the appeal proceedings.

The ninth and tenth auxiliary requests had to be considered as a response to the Board's preliminary opinion, in which the Board had stated that it was inclined to consider novelty in view of D2. The Board had provided a new interpretation of what could constitute a "base plate" in the device disclosed in D2. *Prima facie*, the ninth and tenth auxiliary requests addressed the novelty issues in view of D2 and were clear. In particular, the patent clearly explained what had to be understood by the expression "area with reduced material dimensions". This was an area with a reduction in the height or width of the material, or

with openings or cut-outs in material, as disclosed in paragraphs [0014], [0021] and [0040], and as were visible in Figures 26 and 30 of the patent. Hence, the ninth and tenth auxiliary requests were to be admitted into the appeal proceedings.

The eleventh auxiliary request had been filed only during the oral proceedings because of the exceptional circumstances of the case, in which the Board had formulated a surprising objection for the first time in the preliminary opinion and had not admitted the ninth and tenth auxiliary requests for *prima facie* lack of clarity, this clarity objection having been made in detail by the Board only at the oral proceedings. For fair and equal treatment, this request was to be admitted into the appeal proceedings.

Second auxiliary request - novelty

D2 did not disclose a base plate as defined in claim 1 of the second auxiliary request. The combination of the flexible sheet 721, the top 723 and the base portion 724 was not a plate-like structure within the normal meaning of the term "plate". Moreover, the expression "base plate" implied the the plate served as a support, forming the bottom part of the claimed device. This was also confirmed by paragraph [0112] of the patent. In D2, the only plate that served as a support forming the bottom part of the device in the embodiment in Figure 16 was 721 and/or 724, not the top 723.

Even if this combination of elements was considered to be the base plate according to the claim, the person skilled in the art would have determined that the lower surface of the flexible sheet 721 corresponded to the

proximal side of the base plate as claimed and that the upper surface of the top 723 corresponded to the distal side of the base plate as claimed. It followed that the flexible arms 726 of the top 723 in D2 did not extend from the distal side of the base plate.

D2 did not disclose a flexible part as defined in claim 1 of the second auxiliary request. From the patent as a whole the person skilled in the art understood that the purpose of the flexible part was to reduce the transfer of actions from the fluid delivery part to the subcutaneously positioned section of the cannula. Hence, the flexible part as claimed had to be suitable for this purpose. D2 did not provide any information as to the nature of the flexible sheet 721, which therefore could not be considered to meet the claim requirements.

D2 did not disclose an injection part comprising a cannula part in the form of a two-part unit comprising a first cannula part and a second cannula part, with the first cannula part being fastened unreleasably to the base plate. The base portions 724 provided with the opening 725 from D2 could not be considered to be the first cannula part according to claim 1 of the second auxiliary request because they formed part of the base plate, which had to be distinct from the injection part. Moreover, the part of the base portions 724 comprising the opening 725 was integrally formed in the base portions, not fastened unreleasably to them. The term "fastened" implied that the first cannula part and the base plate were distinct from each other.

D2 did not disclose a fluid delivery part that could be attached to and separated from the base plate during use. According to page 14 of D2, these two elements

could be separated only after use.

For all these reasons, the subject-matter of claim 1 of the second auxiliary request was novel over D2.

Third auxiliary request and auxiliary request 4 - novelty

In claim 1 of the third auxiliary request and claim 1 of auxiliary request 4 it was expressly specified that the flexible part reduced the transfer of actions from the fluid delivery part to the subcutaneously positioned section of the cannula. The flexible sheet 721 in D2 did not fulfil this requirement, as the fluid delivery part was directly connected to the cannula by the base portions 724. Moreover, the second cannula part was not configured to be placed in the first part, with the first part being provided with locking means for locking the cannula in a desired position.

Hence, the subject-matter of claim 1 of both the third auxiliary request and auxiliary request 4 was novel over D2.

VII. The opponent's arguments, where relevant to this decision, can be summarised as follows:

Admittance of novelty objections based on D2 and of the second, third and ninth to eleventh auxiliary requests

The novelty objections based on D2 were to be admitted into the proceedings. Novelty over D2 had been discussed extensively throughout the first-instance proceedings, in particular with respect to the then first auxiliary request during oral proceedings before

the opposition division. An objection of lack of novelty based on D2 against claim 1 as granted had been raised in the statement setting out the grounds of appeal. The proprietor's own interpretation of claim 1 of the second and third auxiliary requests and of claim 1 of auxiliary request 4 with respect to the definition of the flexible part, made in the reply to the opponent's statement of grounds, justified the objections of lack of novelty over D2 raised by letter dated 24 January 2019. The proprietor's reference to point 4.5.1 of the minutes of the oral proceedings before the Opposition Division stating that the opponent had no further objections against auxiliary request 4 had been taken out of context. In view of the positions taken by the Opposition Division during the oral proceedings, it would not have been appropriate to raise objections based on D2 again, since such objections had not been successful against previous requests.

The second and third auxiliary requests had not been presented in the first-instance proceedings. The proprietor wanted to avoid the opposition division making a decision on them. This was not appropriate and these requests were not to be admitted into the appeal proceedings.

The ninth and tenth auxiliary requests were *prima facie* not allowable, as claim 1 of these requests was unclear for multiple reasons. In particular, the definition of the flexible part being constructed of an area with reduced material dimensions was unclear because it was not specified with respect to what the dimensions were reduced. Claims had to be clear on their own, without the need to refer to the description. For this reason the ninth and tenth auxiliary requests were not to be

admitted into the appeal proceedings.

The eleventh auxiliary request had been submitted only during the oral proceedings, in the absence of any exceptional circumstances for it being filed late. Hence, the eleventh auxiliary request was not to be admitted.

Second auxiliary request - novelty

D2 was novelty-destroying for the subject-matter of claim 1 of the second auxiliary request. This claim did not provide any limiting definition as to how a base plate could be constructed. It did not specify that the base plate had to have any supporting function. According to Figure 26 of the opposed patent the base plate could comprise sections protruding away from the patient. Therefore, the combination of 721, 723 and 724 in D2 was a base plate within the meaning of claim 1.

The claim definition of the fastening means extending from the distal side of the base plate did not specify any direction of extension. Therefore, flexible arms 726 in D2 anticipated the means for fastening extending from the distal side of the base plate in claim 1.

The term "flexible" was a relative term and was to be interpreted in the least restrictive way possible when assessing the novelty of claim 1 of the second auxiliary request. There was no reason why the sheet 721 in D2, which was expressly disclosed as being a "flexible sheet", should not have been regarded as being flexible within the meaning of the claim. The ability to reduce the transfer of actions resulted from its flexibility.

According to claim 1 of the second auxiliary request the base plate and the first cannula part did not need to be distinct from each other. The claim merely required that the injection part comprised both of these components. Dependent claim 4 of the second auxiliary request specified that the base plate was provided with a first part of a cannula part. When reading claim 1 in view of dependent claim 4, it was clear that the first cannula part could be part of the base plate in the same way as the means for fastening, which the base plate also comprised. "Fastened unreleasably" only meant that the first cannula part could not be separated from the base plate without destroying or damaging these elements.

D2 also expressly disclosed a fluid delivery part that could be attached to and separated from the base plate during use (page 13, lines 23 to 26).

Therefore, the subject-matter of claim 1 of the second auxiliary request was not novel over D2.

Third auxiliary request and auxiliary request 4 - novelty

The definition in claim 1 of the third auxiliary request and claim 1 of auxiliary request 4 according to which the flexible part reduced the transfer of actions from the fluid delivery part to the subcutaneously positioned section of the cannula lacked any quantitative requirement. By its nature of being flexible, the flexible sheet 721 in D2 reduced the transfer of actions as defined in the claim. The elements 724 and 726 were also flexible, and therefore they contributed to reducing this transfer of actions.

D2 also disclosed a second cannula part with a cannula configured to be placed in the first part (hole 725), the first part being provided with locking means (cooperating with the protrusions 772 of the second cannula part) for locking the cannula in a desired position.

Hence, the subject-matter of claim 1 of both the third auxiliary request and auxiliary request 4 was not novel over D2.

Reasons for the Decision

1. The invention

The invention relates to a device for delivering fluid, as illustrated in Figures 20, 21 and 22 of the patent reproduced below.

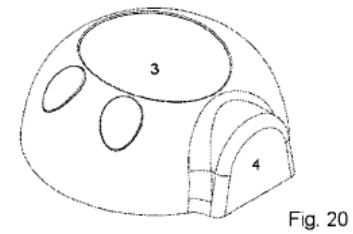
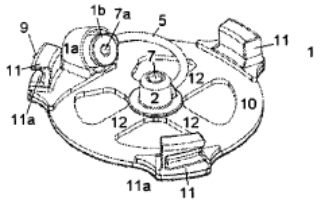
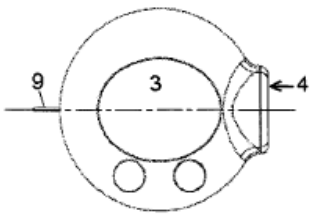


Fig. 20





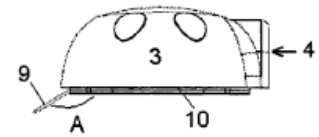


Fig. 21

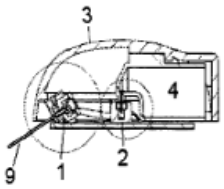


Fig. 22

The device for delivering fluid comprises an injection part and a fluid delivery part (3, 4). The device is typically used for intermittent or continuous administration of a therapeutical substance, such as insulin.

The fluid delivery part comprises a reservoir (4), transfer means, and a housing (3). The fluid delivery part can be used to transfer fluid contained in the reservoir to the injection part, for subcutaneous injection into a patient.

The injection part comprises a base plate (10) with means for fastening (11) the fluid delivery part to the base plate in such a way that the fluid delivery part (3, 4) can be attached to and separated from the base plate (10) during use. The means for fastening (11) extend from the distal side of the base plate.

The injection part also comprises means for fixation of the base plate to the skin of a patient and a cannula part in the form of a two-part unit, with a first cannula part (1a) and a second cannula part (1b). The first cannula part (1a) is fastened unreleasably to the base plate. The second cannula part (1b) is configured to be inserted into the position defined by the first cannula part (1a) and attached to the base plate (10) after the base plate (10) has been positioned on the skin of the patient.

The cannula part comprises a body which, during use, provides a through-going opening leading liquid to a soft cannula (9) extending past the proximal side of the base plate (10). The base plate has a surface corresponding to an inserter device for the cannula part. A flexible part is arranged in an area between the subcutaneously positioned section of the soft cannula (9) and the fluid delivery part (3, 4).

According to the description and claim 1 of the third auxiliary request and claim 1 of auxiliary request 4,

the flexible part is for reducing the transfer of actions from the fluid delivery part to the injection part when the fluid delivery part is affected by touches or movements. This should avoid discomfort or pain for the user (paragraphs [0006] and [0009] of the description).

2. Admittance of novelty objections based on D2 and of the second, third and ninth to eleventh auxiliary requests

2.1 The opponent argued that the second and third auxiliary requests were not to be admitted into the appeal proceedings since they could and should have been filed during the first-instance proceedings.

The second and third auxiliary requests were submitted by the proprietor with the statement of grounds of appeal. Under Article 12(4) RPBA 2007, which applies by virtue of Article 25(2) RPBA 2020, everything presented by the proprietor with the statement of grounds of appeal is to be taken into account by the Board, although the Board still has discretion not to admit requests which could have been presented in the first-instance proceedings.

The Board notes that claim 1 of the second and third auxiliary requests only comprises features which were considered in substance by the Opposition Division in the impugned decision, since they were all present, in essence, in claim 1 of auxiliary request 4.

Under these circumstances the Boards decided to admit the second and third auxiliary requests into the appeal proceedings in accordance with Article 12(4) RPBA 2007.

2.2 In the appeal proceedings, the opponent argued that the subject-matter of claim 1 of the second and third auxiliary requests, and of auxiliary request 4, lacked novelty over D2 for the first time in its submissions dated 24 January 2019, i.e. after the reply to the proprietor's statement of grounds was filed.

Under Article 13(1) RPBA 2020, these objections constitute an amendment to the opponent's appeal case, which is subject to the opponent's justification and may be admitted only at the Board's discretion. This discretion is to be exercised in view of, *inter alia*, the current state of the proceedings, the suitability of the amendment to affect the outcome of the appeal proceedings, and whether the amendment is detrimental to procedural economy.

The opponent provided a justification as to why the amendment was submitted only at that stage of the proceedings (point B.II.1 on page 8 of its submissions of 24 January 2019). It was done swiftly in response to an interpretation of the claimed flexible part presented by the proprietor in its reply to the opponent's statement of grounds for arguing against clarity objections raised by the opponent and concerning the same flexible part. The Board considers that the novelty objections effectively address the issue of claim construction raised by the proprietor. Moreover, D2 was considered by the Opposition Division in the impugned decision and was relied on by the opponent in its statement of grounds of appeal, albeit only in respect of claim 1 of the patent as granted. Hence, the parties are well acquainted with the disclosure of D2. Therefore, considering the novelty objections, which are *prima facie* relevant for the outcome of the appeal proceedings, is not detrimental

to procedural economy.

As regards the proprietor's argument that the opponent had explicitly stated in the oral proceedings before the Opposition Division that it had no further novelty objections in view of D2 against auxiliary request 4, the Board is satisfied by the opponent's explanation that this statement had simply been made in view of the Opposition Division's conclusions on the higher-ranking requests. It would have been useless to try to reopen a discussion on issues which had already been considered.

For these reasons, making use of its discretion in accordance with Article 13(1) RPBA 2020, the Board admitted the novelty objections in view of D2.

2.3 The ninth and tenth auxiliary requests are an amendment to the proprietor's case submitted after the Board's notification of the summons to oral proceedings.

Under Article 13(2) RPBA 2020 any such amendment, in principle, must not be taken into account unless there are exceptional circumstances, which have been justified with cogent reasons by the party concerned. For assessing the admissibility of the amendments the Board may also consider the criteria applicable under Article 13(1) RPBA 2020 (explanatory remarks to the RPBA 2020).

In particular, under Article 13(1) RPBA 2020, in case of an amendment to a patent, it has to be considered whether the proprietor has demonstrated that such an amendment, *prima facie*, does not give rise to new objections.

In the Board's view the definition of the flexible part

being "constructed of an area with reduced material dimensions" in claim 1 of the ninth and tenth auxiliary request is, *prima facie*, unclear and hence contravenes Article 84 EPC. As the opponent pointed out, the claims do not specify with respect to what the dimensions are reduced. This leaves the reader in doubt as to the subject-matter for which protection is sought. Whether or not the description of the patent might explain what should be understood by the expression "area with reduced material dimensions" is not decisive. As the opponent pointed out, the subject-matter of the claims has to be clear on its own, without the need to refer to the description to resolve ambiguities.

For this reason the Board does not admit the ninth and tenth auxiliary requests into the appeal proceedings in accordance with Article 13(2) RPBA.

2.4 The eleventh auxiliary request was only submitted during the oral proceedings.

Under Article 13(2) RPBA 2020 this request must not be taken into account unless there are exceptional circumstances, which have been justified with cogent reasons by the proprietor.

The proprietor argued that the Board had formulated a surprising objection for the first time in the preliminary opinion and had not admitted the ninth and tenth auxiliary request for *prima facie* lack of clarity, this clarity objection having been made in detail only at the oral proceedings.

The ninth and tenth auxiliary requests were filed after the Board's preliminary opinion, according to the proprietor as a response to an objection raised by the

Board for the first time in its written preliminary opinion. The eleventh auxiliary request is supposed to address the same objection, and therefore could and should have already been filed together with them. There is no cogent reason justifying it being filed only on the last possible day of the appeal proceedings, i.e. on the day of the oral proceedings. Under these circumstances, it is not decisive whether or not the eleventh auxiliary overcomes the objection. As regards the *prima facie* lack of clarity which led to the ninth and tenth auxiliary requests not being admitted, the Board notes that it was the proprietor's responsibility that these late-filed requests *prima facie* met the requirements of the EPC for them to be admitted in accordance with Article 13(1) and (2) RPBA 2020. Not meeting these requirements cannot provide any cogent reasons for filing further requests.

Hence, the Board does not admit the eleventh auxiliary request into the appeal proceedings in accordance with Article 13(2) RPBA.

3. Second auxiliary request - novelty

3.1 D2 discloses a device for delivering fluid (page 1, lines 11 to 13), depicted in Figures 1, 15 and 16 reproduced below.

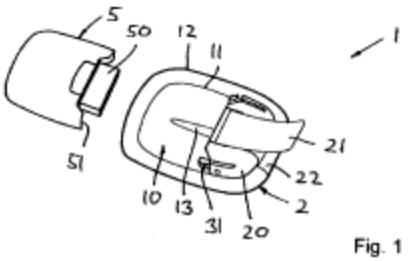


Fig. 1

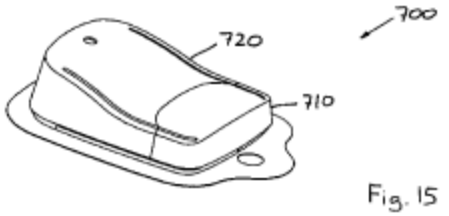


Fig. 15

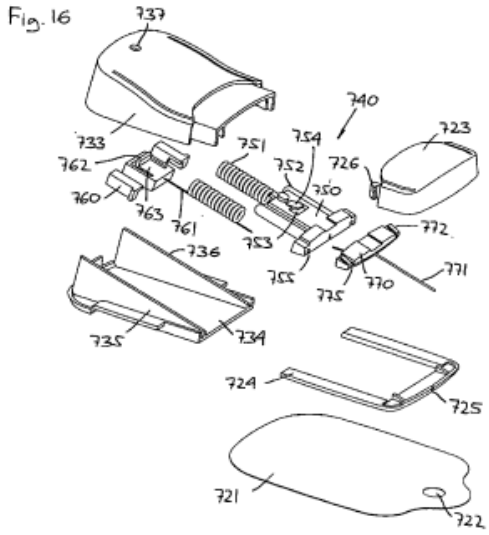


Fig. 16

The device comprises an injection part (patch unit 710) and a fluid delivery part (reservoir unit 5, page 23, line 34 to page 24, line 4).

The fluid delivery part comprises a reservoir, transfer means, and a housing (page 13, line 32 to page 14, line 5).

The injection part comprises a base plate (721, 723 and 724 together, page 21, line 34 to page 22, line 3) comprising means for fastening (housing top 723, provided with hooks 726) the fluid delivery part to the base plate in such a way that the fluid delivery part can be attached to and separated from the base plate during use (page 13, lines 23 to 26, page 13, line 32 to page 14, line 5 and page 14, lines 28 to 31), the means for fastening extending from the distal side of the base plate; and means for fixation (lower adhesive surface of the flexible sheet 721, page 21, line 34 to page 22, line 3) of the base plate to the skin of a patient.

The injection part also comprises a cannula part with a

body (770) which during use provides a through-going opening leading liquid to a soft cannula (771) extending past the proximal side of the base plate.

The cannula part is a two-part unit comprising a first cannula part (the part of the lower housing 724 provided with the opening 725) and a second cannula part (the part 770 provided with the cannula 771) wherein the first cannula part is fastened unreleasably to the base plate and the second cannula part is configured to be inserted into the position defined by the first cannula part (through-opening 725) and attached to the base plate after the base plate has been positioned on the skin of the patient (page 22, line 31 to page 23, line 7).

The base plate comprises a surface corresponding to an inserter device for the cannula part (surface of the flexible sheet 721 below the inserter unit 720).

A flexible part (flexible sheet 721) is arranged in an area between a subcutaneously positioned section of the soft cannula and the fluid delivery part.

Hence, D2 discloses all the features of claim 1 of the second auxiliary request.

3.2 The proprietor argued that the combination of the flexible sheet 721, the top 723 and the base portion 724 was not a plate-like structure within the normal meaning of the term "plate"; however, according to the patent in suit, the base plate with the means for fastening does not have to be flat (see, for example, the base plate 19 with protruding means for fastening 11 in Figures 20, 4 and 26).

The proprietor also argued that the expression "base plate" implied that the plate served as a support; however, the claim does not specify this. In general a base could simply mean the bottom part of a device, which is what the combination of elements 721, 723 and 724 produces in the device of D2. Whether paragraph [0112] or other parts of the description of the patent might imply that the base plate may function as a support in a device according to the patent is not decisive, as the claims may well generalise the teaching of the description.

The proprietor also argued that the flexible arms 726 did not extend from the distal side of the base plate, hence they did not meet the claim requirements; however, as also pointed out in the Board's preliminary opinion, the top 723 can be considered to be the means for fastening according to claim 1 of the second auxiliary request. The flexible arms 726 of the top 723 are the elements which perform the fastening. The top 723 extends distally from the surface defined by the flexible sheet 721.

A further argument by the proprietor was that D2 did not disclose that the element 721 was a flexible part within the meaning of claim 1 of the second auxiliary request; however, D2 expressly discloses the element 721 as being a "flexible sheet" (page 21, line 34 to page 22, line 1). Again, whether the description of the patent might disclose further specific features of the flexible sheet is not decisive, since the claims may well generalise the teaching of the description.

The proprietor also argued that D2 did not disclose an injection part comprising a cannula part in the form of a two-part unit comprising a first cannula part and a

second cannula part, with the first cannula part being fastened unreleasably to the base plate. More specifically, it argued that the transverse part of the element 724 provided with the opening 725 in D2 could not be considered to be the claimed first cannula part because it formed part of the base plate; however, in the embodiment of Figure 20 of the patent, too, the first cannula part 1a belongs to the base plate 10, which is in accordance with claim 4 of the second auxiliary request. Whether the transverse part of the element 724 comprising the opening 725 is integrally formed in the element 724 is not decisive. Still, the whole element 724, hence also the transverse part with the opening 725, is fastened unreleasably to the flexible element 721. After having been fastened together, they form part of the base plate as defined in claim 1 of auxiliary request 2 in a manner similar to that of the cannula part 1a and the plate 10 (Figure 20) in the patent in suit.

The proprietor's argument that D2 did not disclose a fluid delivery part that could be attached to and separated from the base plate during use is not convincing either. D2 explicitly discloses this feature on page 13, lines 23 to 26, in which it is stated that the coupling between the fluid delivery part, identified as the "reservoir unit", and the base plate, part of a "needle unit", allows "the reservoir unit to be releasable secured to the needle unit in the situation of use".

3.3 It follows that the second auxiliary request cannot be allowed for lack of novelty (Article 54(1) and (2) EPC) of the subject-matter of claim 1 over D2.

4. Third auxiliary request and auxiliary request 4 - novelty

4.1 In claim 1 of the third auxiliary request it is additionally specified that the flexible part reduces the transfer of actions from the fluid delivery part to the subcutaneously positioned section of the cannula.

The proprietor argued that the flexible sheet 721 in D2 did not fulfil this requirement, as the fluid delivery part was directly connected to the cannula by the base portions 724.

This argument is not convincing. Claim 1 of the third auxiliary request does not specify any structural feature for reducing the transfer or any quantitative requirement. The flexible nature of the element 721, which is interposed between the skin of the patient in which the cannula is positioned, and the fluid delivery part inherently reduces the transfer of actions. Moreover, the other elements involved in the coupling between the fluid delivery part and the cannula, e.g. the hooks 726, are also flexible. Hence, they allow the transfer of actions to be reduced, as defined in the claim.

4.2 The proprietor also argued that the subject-matter of claim 1 of auxiliary request 4 was novel by virtue of the second cannula part being configured to be placed in the first part, with the first part being provided with locking means for locking the cannula in a desired position.

However, D2 discloses that the second cannula part (770 provided with the cannula 771) is configured to be placed in the first part by introducing the cannula 771

into the opening 725 in the first cannula part. Moreover, D2 discloses locking means of the first cannula part for locking the cannula in a desired position (the elements on the transverse part of 724 with the opening 725 which cooperate with the protrusions 772 of the second cannula part, page 22, lines 16 to 18).

4.3 It follows that the subject-matter of claim 1 of the third auxiliary request and of claim 1 of auxiliary request 4 is also anticipated by D2.

Hence, the third auxiliary request and auxiliary request 4 cannot be allowed for lack of novelty (Article 54(1) and (2) EPC).

5. Since none of the claim requests in the proceedings is allowable, the patent must be revoked in accordance with Article 101(3)(b) EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairman:

D. Hampe M. Alvazzi Delfrate

Decision electronically authenticated