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**Datasheet for the decision
of 12 September 2022**

Case Number: T 0272/15 - 3.2.02

Application Number: 05019774.8

Publication Number: 1762259

IPC: A61M5/158, A61M25/06

Language of the proceedings: EN

Title of invention:

Inserter for an infusion set with a first and second spring units

Patent Proprietor:

Unomedical A/S

Opponent:

Roche Diabetes Care AG (CH) /
Roche Diagnostics GmbH (DE)

Relevant legal provisions:

RPBA 2020 Art. 13(2)

EPC Art. 53(c), 54, 56, 57, 83, 84, 123(2), 123(3)

Keyword:

Late-filed document - admitted (no)

Late-filed request - admitted in first-instance proceedings
(yes)

Amendments - added subject-matter (main request, auxiliary
request 1 : yes, auxiliary request 2 : no) - extension of
scope of protection (auxiliary request 2 : no)

Claims - clarity (yes)

Sufficiency of disclosure - (yes)

Industrial application - (yes)

Exceptions to patentability - method for treatment by surgery
- (no)

Novelty - (yes)

Inventive step - (yes)

Decisions cited:

T 1544/08



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Case Number: T 0272/15 - 3.2.02

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

Appellant: Unomedical A/S
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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 28 November
2014 revoking European patent No. 1762259
pursuant to Article 101(3) (b) EPC.**

Composition of the Board:

Chairman M. Alvazzi Delfrate
Members: S. Dennler
N. Obrovski

Summary of Facts and Submissions

- I. The patent proprietor filed this appeal against the Opposition Division's decision to revoke the contested patent.
- II. In its decision, the Opposition Division held that the patent and the invention to which it related did not meet the requirements of the EPC. Claim 1 of the patent as granted and claim 1 of the first auxiliary request were both found to comprise added subject-matter, and claim 1 of the second auxiliary request was found to lack novelty over the following document:

E1 WO 2005/046780 A1

- III. The Board provided its preliminary opinion in its communication under Article 15(1) RPBA 2020 dated 22 July 2020.
- IV. Oral proceedings before the Board were held on 12 September 2022.
- V. The appellant (proprietor) requested that the decision under appeal be set aside and that the patent be maintained as granted, as its main request, or, as an auxiliary measure, that it be maintained on the basis of one of auxiliary requests 1 to 3, filed with the statement of grounds of appeal, or one of auxiliary requests 4 to 6, filed with the submission dated 2 November 2020. Auxiliary requests 1 and 2 are identical, respectively, to the first and second auxiliary requests on which the decision under appeal was based.

VI. The respondent (opponent) requested that the appeal be dismissed.

VII. This decision also refers to the following documents:

- E3** WO 02/081012 A2
- E4** WO 2004/098683 A1
- E5** US 2003/0060781 A1
- E8** US 4,388,925
- E9** US 2004/0133164 A1
- E10** WO 03/090509 A2
- E11** US 2005/0085839 A1
- E13** US 2005/0096586 A1
- E14** US 2007/0093754 A1
- E15** Figures 1 to 5 filed with the appellant's submission dated 2 November 2020
- E16** Figures 1 to 5 filed with the appellant's submission dated 17 May 2021

VIII. Claim 1 of the **main request** (patent as granted) reads as follows (amendments compared to claim 1 as originally filed highlighted by the Board):

*"An inserter for an infusion set comprising a housing (1), a carrier body (2) carrying an infusion part (8), a needle hub (3) provided with an insertion needle (6), a first moving unit (4) bringing the carrier body (2) and the needle hub (3) to a forward position and, a second moving unit (5) bringing the ~~carrier body (2)~~ needle hub (3) to a retracted position, **characterized in that** the inserter has and means for activation which should be activated at least once in order to bring the carrier body (2) and the needle hub (3) from a retracted to a forward position,*

and the needle hub (3) back from the forward to the retracted position,

characterized in that

the first moving unit (4) and the second moving unit (5) both are connected to a distal surface of the carrier body (2)."

IX. Claim 1 of **auxiliary request 1** reads as follows (amendments compared to claim 1 as originally filed highlighted by the Board):

"An inserter for an infusion set, comprising a housing (1), a carrier body (2) carrying an infusion part (8), a needle hub (3), a first moving spring unit (4) ~~bringing the carrier body (2) to a forward position and a second moving spring unit (5) bringing the carrier body (2) to a retracted position,~~ **characterized in that** where

- the housing (1) is provided with guiding means (1a, 1b) on the internal surface for guiding the movement of the carrier body (2),

- the needle hub (3) comprises an insertion needle (6) for piercing of the skin,

- the carrier body (2) has a retracted and a forward position, and in the retracted position before insertion, the carrier body (2) and the needle hub (3) are locked to each other,

- the carrier body (2) is provided with guiding means (2a) corresponding to the guiding means (1a, 1b) on the housing (1),

- the first spring unit (4) is biasing the housing (1) and the carrier body (2) for bringing the carrier body (2) and the needle hub (3) to the forward position,

- the second spring unit (5) is biasing the carrier body (2) and the needle hub (3) for bringing the needle hub (3) to a retracted position,

- the inserter ~~has~~ comprising means for activation which should be activated ~~at least~~ once in order to bring the carrier body (2) and the needle hub (3) from a ~~the~~ retracted to a ~~the~~ forward position, and ~~the~~ needle hub (3) back from the forward to the retracted position,

characterized in that the first and the second spring units (4, 5) both are connected to a distal surface of the carrier body (2)."

- X. Claim 1 of **auxiliary request 2** reads as follows (amendments compared to claim 1 as originally filed highlighted by the Board):

"An inserter for an infusion set, comprising a housing (1), a carrier body (2) carrying an infusion part (8), a needle hub (3), a first ~~compression spring moving unit~~ (4) ~~bringing the carrier body (2) to a forward position~~ and a second ~~compression spring moving unit~~ (5) ~~bringing the carrier body (2) to a retracted position,~~

where

- the housing (1) is provided with guiding means (1a, 1b) on the internal surface for guiding the movement of the carrier body (2),

- the needle hub (3) comprises an insertion needle (6) for piercing of the skin,

- the carrier body (2) has a retracted and a forward position, and in the retracted position before insertion, the carrier body (2) and the needle hub (3) are locked to each other,

- the carrier body (2) is provided with guiding means (2a) corresponding to the guiding means (1a, 1b) on the housing (1),

- the first compression spring (4) is biasing the housing (1) and the carrier body (2) for bringing the carrier body (2) and the needle hub (3) to the forward position,

- the second compression spring (5) is biasing the carrier body (2) and the needle hub (3) for bringing the needle hub (3) to a retracted position,

~~- characterized in that~~ the inserter ~~has means for activation which should be~~ being activated by unlocking the carrier body (2) from the housing (1) whereby upon activation the first compression spring (4) at least once in order to brings the carrier body (2) and the needle hub (3) from a the retracted to a the forward position, and the second compression spring (5) brings the needle hub (3) back from the forward to the retracted position,

wherein the first and the second compression springs (4, 5) both are connected to a distal surface of the carrier body (2)."

XI. The **appellant's arguments** relevant for this decision can be summarised as follows.

Admittance of documents E14 and E15

E14 was a US patent application which claimed priority from the European application from which the contested patent had been granted. The figures shown in E15 were the original figures filed at the USPTO for E14. Apart from a few differences in the reference signs, these

figures corresponded to those of the contested patent but were clearer.

The appellant had filed E14 and E15 in response to the respondent's submission dated 24 February 2015 that it had deliberately withheld E14 for tactical reasons, this possibly constituting an abuse of procedure, and in response to the fact that the Board had mentioned this document in its preliminary opinion. In any case, although E14 and E15 had not been introduced into the proceedings, they were known by both parties and the Board. To remove any uncertainty or ambiguity, E14 and E15 should therefore be admitted into the appeal proceedings.

Admittance of document E16

E16 consisted of the original greyscale Figures 1 to 5 which had been filed as part of the original application on which the contested patent was based. The black-and-white figures of limited contrast contained in the European Patent Register and in the contested patent differed from these greyscale figures only due to the loss of quality resulting from their scanning upon filing. In line with T 1544/08, these original greyscale figures, being of better quality, should be taken into account instead of their black-and-white scanned copies when assessing the content of the application as filed.

These original figures could not have been filed earlier because of the unavoidable time needed to locate them given that they had been originally filed by another representative. As they were part of the application documents originally filed, their filing did not amount to an amendment of the appellant's

appeal case. Rather, they were already in the proceedings and were therefore to be taken into account in the appeal proceedings. These figures should at least be admitted because they merely confirmed what was already on file as part of the application as filed.

Main request and auxiliary request 1 - added subject-matter

The original application did not disclose separate, unrelated embodiments but rather the same inserter described at different levels of generalisation throughout the description and the claims originally filed. Accordingly, there was no new subject-matter arising from defining the first and second moving units as being connected to a distal surface of the carrier body because this feature would have been understood to be generally applicable to the inserter defined more generally in original claim 1. This feature would thus not be read as being inextricably linked to the further features of the first and second spring units respectively biasing the carrier body and the housing, and the carrier body and the needle hub, and of the needle hub being locked with the carrier body in the retracted position before activation of the inserter. These further features merely related to a more limited definition of the inserter disclosed in original claim 1.

Concerning the activation mechanism defined in original claims 1 and 2 and on page 4, lines 7-9, the person skilled in the art would have recognised that there was an error in that definition. From the whole application as originally filed, the person skilled in the art would have indeed directly and unambiguously understood

that it was the needle hub, and not the carrier body, which was retracted by the second moving unit from the forward position, as the application only ever described it. The definition of the means for activation given in claim 1 of the main request and auxiliary request 1 therefore did not constitute added subject-matter.

Admittance of auxiliary request 2

The appellant did not comment on this issue.

Auxiliary request 2 - added subject-matter

Claim 1 of auxiliary request 2 met the requirements of Article 123(2) EPC.

Auxiliary request 2 - novelty in view of E1

The subject-matter of claim 1 of auxiliary request 2 was novel over the embodiment shown in Figures 97-102 of E1.

The retainer body 1978, main body 1980 and lock member 1962 were consistently presented in E1 as separate bodies. The person skilled in the art would not regard them as forming in combination a "carrier body". Only the retainer body 1978 alone could be identified as a carrier body.

A lock between two mechanical parts required, in the context of both the contested patent and E1 itself, that the parts be shaped specifically and mutually engage such that they were fastened or secured to each other. At least one of the parts had to deform to allow for the parts to disengage and become unlocked. This

was also explicitly shown in E1, Figure 42, where parts 220 and 250 were described as being "locked" to each other via barbs 223 engaging corresponding lips 272 (page 13, line 31). Thus, a "lock" in the context of the contested patent required more than a simple tight-fit or friction engagement.

Figure 102 showed only the final configuration of the inserter ready for insertion of the infusion part. The fact that the lock member 1962, the needle hub 1964 and the retainer body 1978 were movable longitudinally did not necessarily mean that these parts were "locked" - or in fact even fastened - to each other and had to move as a single unit during the insertion and retraction phases. Rather, this final configuration could also be achieved by a tight fit of the components in the longitudinal direction and/or the bias of spring 1966. E1 did not disclose that spring 1966 was fully compressed.

The needle hub 1965 and the retainer body 1978 were shown in Figure 102 merely as abutting each other. Separating them required only a simple longitudinal relative movement, possibly to overcome some friction or the bias of the spring, but no deformation.

Thus, E1 failed to directly and unambiguously disclose that in the retracted position before insertion, the retainer body 1978 as the carrier body and the needle hub were locked to each other. Nor did E1 disclose directly and unambiguously that before insertion the retainer body 1978 was locked to the housing and that it then had to be unlocked to activate the inserter. Instead, the inserter of E1 relied on a separate component, the lock member 1962, being unlocked from the housing for activation. Since the lock member 1962

and the retainer body 1978 were not necessarily fastened to each other before activation, unlocking the lock member from the housing could not be regarded as causing the unlocking of the retainer body itself from the housing.

Auxiliary request 2 - inventive step starting from E1

The objective technical problem to be solved starting from E1 could be formulated as making the inserter more secure and easier to use, as explained in the contested patent (paragraphs [0009] and [0025]).

Proceeding from E1, the person skilled in the art would have had no incentive to include these distinguishing features in the inserter of Figure 102. This known inserter already had means for activation, and adding a further lock would have only complicated the internal mechanism, thus going against the teaching of E1 (page 1, lines 19-21; page 2, lines 4-6). There were many other ways to make the inserter more secure, for example, by adding a protective cap or using suitable materials. The respondent's inventive-step objection was based on hindsight.

It followed that the subject-matter of claim 1 of auxiliary request 2 involved an inventive step over E1.

Auxiliary request 2 - further objections submitted by the respondent in writing

The further objections against auxiliary request 2 under Articles 53(c), 54(1) and (2), 56, 83, 84, and 123(2) EPC raised by the respondent in writing were without merit.

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

Admittance of documents E14 and E15

Despite the appellant's allegation that the figures shown in E14 and E15 were similar to those of the contested patent, E14 and E15 were neither legally nor factually related to the current proceedings. E14 did not even belong to the prior art under Article 54(2) EPC. In the whole first-instance proceedings, neither the opponent, nor the proprietor, nor the Opposition Division had ever relied on E14. E14 was, however, surprisingly mentioned in the minutes of the second oral proceedings before the Opposition Division. The respondent thus had to assume that the Opposition Division had considered this document in its decision although it was not part of the proceedings. This constituted a severe procedural error.

E14 and E15 should not be taken into account in the appeal proceedings to avoid any bias when assessing the original disclosure of the application from which the contested patent had been granted.

Admittance of document E16

While the appellant's assertion that the figures shown in E16 were those originally filed for the application from which the contested patent had been granted could be correct, this was nevertheless doubtful. The respondent was not in a position to verify this allegation. Therefore, E16 was to be considered an amendment to the appellant's appeal case, subject to Article 13(2) RPBA 2020.

There were, however, no exceptional circumstances justifying the admittance of this document at such a very late stage of the proceedings, more than ten years after the start of the opposition proceedings. T 1544/08, which did not address admittance issues, was irrelevant. E16 should therefore not be taken into account in the appeal proceedings.

Main request and auxiliary request 1 - added subject-matter

Claim 1 of the main request contained added subject-matter in breach of Article 123(2) EPC.

Claim 1 combined features that had originally been disclosed in the context of different independent claims and different, unrelated embodiments. There was no reason for the person skilled in the art to believe that original claims 1 and 2 and page 4, lines 1 to 9 included any error. Even if there were some doubts about the consistency of the different embodiments, it would not be unambiguously clear that "carrier body" was used in error in four places, which were all consistent, let alone that it would have to be replaced by "needle hub" in exactly those four places.

The feature according to which the first and second moving units were both connected to a distal surface of the carrier body, which had been added as a characterising feature in claim 1 of the main request, had not originally been defined in independent claim 1 but in claim 6, which was dependent on independent claim 5. This feature could not be isolated from the other features originally disclosed in claim 5 in combination for this embodiment. Omitting these features from claim 1 of the main request resulted in

an intermediate generalisation unallowable under Article 123(2) EPC.

Also, the definition of the means for activation in claim 1 of the main request constituted added subject-matter.

Claim 1 of auxiliary request 1 defined first and second spring units. However, there was no support in the application as originally filed for spring units the biasing of which was directly related to "bringing the carrier body and the needle hub to the forward position" and to "bringing the needle hub to a retracted position", respectively, as specified in claim 1. Therefore, claim 1 of auxiliary request 1 also contained added subject-matter in breach of Article 123(2) EPC.

Admittance of auxiliary request 2

Auxiliary request 2 was identical to the second auxiliary request on which the decision under appeal was based. This request had been filed during the first oral proceedings before the Opposition Division, hence late. Consequently, auxiliary request 2 should not be admitted in the appeal proceedings.

Auxiliary request 2 - added subject-matter

Claim 1 of auxiliary request 2 infringed Article 123(2) EPC for the same reasons as claim 1 of auxiliary request 1 did.

Moreover, claim 1 of auxiliary request 2 was directed to the embodiment disclosed on page 6, line 12 to page 10, line 17 of the original description. This was

reflected by the reference to "compression springs", which were only disclosed for this embodiment. However, several additional features originally disclosed were also involved to carry out the claimed unlocking and forward/backward movements of the various parts. Omitting these additional features in claim 1 resulted in an unallowable intermediate generalisation. Defining the activation of the inserter "by unlocking the carrier body from the housing" also necessitated the inclusion of the only enabling disclosure, namely the arrangement described on page 9, lines 18-27. Similarly, the disclosure on page 8, line 11 to page 9, line 6 had also to be included in claim 1.

Furthermore, the back references defined in the dependent claims of auxiliary request 2 did not correspond to those in the original dependent claims. This resulted in subject-matter extending beyond the original disclosure, in breach of Article 123(2) EPC.

Auxiliary request 2 - novelty over E1

The subject-matter of claim 1 of auxiliary request 2 was not novel over the embodiment disclosed in Figures 97 to 102 of E1. E1 disclosed the two features of claim 1 according to which in the retracted position before insertion, the carrier body and the needle hub were locked to each other, and the inserter was activated by unlocking the carrier body from the housing.

Under one interpretation, the retainer body 1978 alone could be regarded as a "carrier body" carrying the infusion part 1970.

E1 disclosed on page 26, lines 16-29 that the lock member 1962, the needle hub 1964 and the retainer body 1978 were movable longitudinally. Once the infusion part 1970 had been loaded onto the retainer body 1978, the lock member 1962 had to be moved upwards by the patient using protrusions 1974 to arrive at the configuration shown in Figure 102, in which the inserter was ready for insertion. Thus, by retracting the lock member 1962, the patient had also retracted the infusion part 1970, the retainer body 1978, the needle hub 1965 and the main body 1980. This was only possible if all these elements were fastened, thus locked, to each other, for example by friction. Otherwise, they would fall apart and would not stay in the configuration shown in Figure 102, which was disclosed as ready for insertion. Thus, E1 disclosed that, in the retracted position before insertion, the carrier body and the needle hub were locked to each other.

In this position, the lock member 1962 was locked to the housing 1958 via barbs 1956. The inserter was then activated by pressing cap 1952, which unlocked the lock member 1962 from the housing so that it was moved downwards by the first spring 1960. Since the retainer body 1978 was initially locked to the lock member 1962 as discussed above, it followed that unlocking the lock member also unlocked the retainer body 1978. Hence, E1 also disclosed that the inserter was activated by unlocking the carrier body from the housing.

Under a second interpretation, the lock member 1962, the main body 1980 and the retainer body 1978, which moved as a single unit during both the insertion and retraction phases, could alternatively be regarded as

forming in combination the "carrier body", which led to the same conclusions.

In this second interpretation, the barbs 1956 of the lock member 1962 thus belonged to the carrier body. It followed that activating the inserter by pushing the cap 1952 to disengage the barbs from the housing actually unlocked the carrier body from the housing.

Similarly, the carrier body included the main body 1980. In the retracted position before insertion, the upward end of barbs 1964 of the needle hub engaged the downward projections 1988 of the main body 1980 under the bias of the second spring 1966. Therefore, in this position, the needle hub was locked to the main body and thus to the carrier body.

Auxiliary request 2 - inventive step starting from E1

If these features were to be found novel over E1, they would in any event not lend inventive step to the subject-matter of claim 1 of auxiliary request 2.

The objective technical problem starting from E1 could indeed be formulated as making the inserter more secure. Contrary to the appellant's assertion, a lock between the carrier body and the needle hub would not make the inserter easier to use.

Starting from E1, it would have been obvious to the person skilled in the art facing this problem to replace the friction-fit between the needle hub and the carrier body with a locking mechanism based on cooperating parts, such as hooks or barbs, so that these two parts were locked to each other in the retraction position before insertion. It would also

have been obvious to modify the activation mechanism of the inserter so that the inserter was activated by unlocking the carrier body from the housing.

The person skilled in the art would therefore have arrived at the subject-matter of claim 1 without an inventive step.

Auxiliary request 2 - further objections submitted by the respondent in writing

The following objections against auxiliary request 2 were raised by the respondent in its written submissions.

(a) Extension of scope of protection

The scope of protection of claim 1 of auxiliary request 2 had been extended compared to that of claim 1 as granted, contrary to the requirements of Article 123(3) EPC.

In claim 1 of auxiliary request 2, the expressions "moving unit" present in claim 1 as granted had been replaced by the expression "compression spring". While the meanings of these expressions might overlap, they were not identical. Hence, the scope of protection of claim 1 of auxiliary request 2 also covered compression springs that were not moving units, for example, compression springs that biased certain elements but did not move them.

Moreover, the "means for activation that should be activated at least once" defined in claim 1 as granted had been replaced by the mere definition that the inserter was "activated by unlocking the carrier body

from the housing". Thus, the scope of protection of claim 1 of auxiliary request 2 also covered inserters deprived of "means for activation".

(b) Lack of clarity

Claim 1 of auxiliary request 2 was unclear, contrary to the requirements of Article 84 EPC. The lack of clarity resulted from the amendments made in claim 1, which did not consist of the mere combination of granted claims.

Claim 1 of auxiliary request 2 did define guiding means on the housing and the carrier body for guiding the movement of the carrier body. However, it was not recognisable for the person skilled in the art if and how that movement of the carrier body was related to the status change of the carrier body and the needle hub defined by the features "for bringing the carrier body (2) and the needle hub (3) to the forward position" and "for bringing the needle hub (3) to a retracted position", which had been inserted into claim 1.

The meaning of the expression "for piercing of the skin" in claim 1 was also unclear if claim 1 was intended to exclude the patient's skin.

It was also not clearly defined how the "biasing" mentioned in claim 1 was acting, for example, if the spring unit pulled the two biased elements together, pushed them apart or biased them in another way. Moreover, it was unclear whether the feature "the first compression spring (4) is biasing the housing (1) and the carrier body (2)" was functionally related to the status change of the carrier body and the needle hub specified by "for bringing the carrier body (2) and the

needle hub (3) to the forward position". The same objection applied to the biasing achieved by the second compression spring.

(c) Insufficiency of disclosure

The patent as amended according to auxiliary request 2 did not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

Due to their poor quality, the figures of the patent did not contain any exploitable information. The description, not having the support of any illustrating figure to explain the various components and their interaction, was not clear enough to be understood without considerable, undue research effort.

Certain features were defined in very generic terms. The sole textual description of the embodiments disclosed did not enable the person skilled in the art to carry out the invention over the full scope of the claims. This concerned, for example, the "carrier body carrying an infusion part".

Moreover, the person skilled in the art would not be able to build an inserter with guiding means for guiding the movement of the carrier body while allowing the two forward and retracted positions defined in claim 1. It was also unclear how the inserter could actually be actuated between these two positions under the effect of the biasing of the compression springs.

(d) Exception to patentability

Due to the insertion of the expression "for piercing of the skin", claim 1 of auxiliary request 2 could be interpreted as a use claim directed to a method that comprised the step of piercing of the patient's skin, hence a surgical step. Claim 1 thus comprised subject-matter excluded from patentability under Article 53(c) EPC.

(e) Industrial applicability

Due to the expression "for piercing of the skin", the subject-matter of claim 1 of auxiliary request 2 could also be interpreted as including the patient to which the device is applied. As a result, it was not industrially applicable, in breach of Article 57 EPC.

(f) Lack of novelty in view of E3, E4 and E10

The subject-matter of claim 1 of auxiliary request 2 also lacked novelty in view of the inserters disclosed in E3, Figures 9-12 and Figures 13-15; E4, Figures 10A-10D; E10, Figures 13A-13C and Figures 14A-14D.

In the embodiment of E3, Figures 13-15, compression spring 31 served both as a first compression spring and a second compression spring. Regarding the other cited embodiments, the lack of novelty resulted from, *inter alia*, the fact that the expression "the spring is biasing feature A and feature B" could also mean that the spring biased both features A and B against a further, unspecified feature C, or that the spring biased one of these features towards the other.

(g) Lack of inventive step starting from E4, E5, E8, E9, E10, E11, E13

The subject-matter of claim 1 of auxiliary request 2 also lacked inventive step over each of the inserters disclosed in E4, Figures 9A-9C and Figures 10A-10D; E5, Figures 1-5; E8, Figures 1-9; E9, Figures 13-33; E10, Figures 23A-23H; E11, Figures 1-5; E13, Figures 1-6, each respectively considered as the starting point.

The attacks starting from E4, Figures 10A-10D as well as from E9, E10 and E13 also relied on alternative interpretations of the expression "is biasing" as argued for novelty.

It would have been a mere routine design task of replacing the leaf spring and extension springs in the embodiment of E4, Figures 9A-9C with two compression springs.

The person skilled in the art would also have obviously implemented a retraction mechanism in the inserter of E5 to retract the insertion needle after inserting the infusion part, instead of covering it with a safety cap.

The spring-actuated mechanisms of the automatic lancet devices disclosed in E8 and E11 were very similar to the mechanism defined in claim 1. It would have been obvious to couple an infusion part to those mechanisms to use them as inserters for an infusion set.

Reasons for the Decision

1. The subject-matter of the contested patent

The contested patent relates to an automatic inserter for inserting an infusion part into a patient's body (paragraph [0001]). This inserter comprises, within a

housing, a needle hub with an insertion needle and a carrier body carrying the infusion part. Upon activation by the patient, a self-actuated mechanism automatically moves the carrier body with the infusion part towards the skin, thus inserting the needle and a cannula of the infusion part into the skin, and then retracts the needle into the housing, leaving the infusion part in place on the skin while protecting the patient from further contact with the needle.

The patent proposes a mechanism that aims at providing a simple, inexpensive inserter that is easy and safe for the user to handle during use and safe to dispose of after use (paragraph [0009]).

2. Admittance of documents E14 and E15

2.1 It is undisputed between the parties that the patent application E14 and the figures E15 were not filed in the first-instance proceedings but for the first time in the appeal proceedings with the appellant's submission dated 2 November 2020. Moreover, it is also common ground that the figures in E15 are not part of the content of the application as filed for the contested patent; they are the original figures filed for E14.

The filing of these documents is therefore an amendment to the appellant's appeal case made after the notification of the summons to attend oral proceedings before the Board. Accordingly, their admittance into the appeal proceedings is subject to Article 13(2) RPBA 2020, under which any amendment to a party's appeal case made at this stage of the proceedings must, in principle, not be taken into account unless there are

exceptional circumstances justified with cogent reasons by the party concerned.

- 2.2 As put forward by the appellant, the Board mentioned E14 in its communication under Article 15(1) RPBA 2020 (point 2). However, the Board only pointed out that there was no indication in the decision under appeal that the Opposition Division had based its decision, even partly, on E14 and that the respondent's allegation that the Opposition Division had committed a procedural error thus seemed unfounded. The Board has not changed its opinion on these points, which were not addressed again by the parties at the oral proceedings before the Board. In any case, contrary to the appellant's view, the statement in question cannot justify admitting E14 and E15 into the proceedings.

The appellant also argued that the respondent had refrained from filing E14 for tactical reasons, this possibly constituting an abuse of procedure. The Board disagrees. It was up to the respondent to make its own appeal case and decide whether it needed to file E14 in support of it. In any case, the indication in the respondent's submission dated 24 February 2015 that it had deliberately not filed E14 cannot justify the admittance of E14 and E15.

The Board further notes that the appellant could have filed these documents earlier. The appellant must have been aware of these documents as E14 was indeed mentioned in the minutes of the second oral proceedings before the Opposition Division dated 28 November 2014 (page 1 of Form 2906, first paragraph). Moreover, the appellant must have known about E14 even earlier because it claims priority from the application from which the contested patent was granted. Nevertheless,

the appellant has not submitted any reasons why it did not file E14 and E15 earlier.

2.3 With regard to *prima facie* relevance, it is in any event irrelevant that the contents of E14 and E15 might have some similarities with that of the contested patent as asserted by the appellant. As E14 and E15 are not part of the content of the application as filed for the contested patent, they cannot be relied on to compensate for an alleged poor quality of the figures of the patent, especially when assessing added subject-matter or interpreting the text of the patent.

2.4 For these reasons, the Board decided not to admit documents E14 and E15 into the appeal proceedings.

3. Admittance of document E16

3.1 The appellant stated that the figures in E16 were those which had been originally filed as part of the application documents forming the application on which the contested patent is based. These figures at least confirmed what was already on file as part of the application as filed.

3.2 While there may be some overall resemblances between these greyscale figures and those in black and white found in the contested patent and in the European Patent Register for the corresponding application, the lack of contrast in the latter is such that the Board cannot assess the veracity of the appellant's allegation.

In these circumstances and in the absence of any additional supporting evidence such as a witness statement or affidavit, document E16 must be regarded

as further evidence filed after the notification of the summons to oral proceedings. This constitutes an amendment of the appellant's appeal case, which is subject to Article 13(2) RPBA 2020.

- 3.3 The appellant explained that it could not have filed these figures earlier because they had originally been filed by another representative and that it had taken a long time to find them.

A change of representative, however, is not a cogent reason that could justify the admittance of these figures at such a late stage of the proceedings. In the Board's view, this applies all the more to a document alleged to be part of the original application documents on which the contested patent is based.

Hence, the Board decided not to admit E16 into the appeal proceedings either.

4. Main request - added subject-matter

- 4.1 Claim 1 of the main request is based on claim 1 as originally filed with, *inter alia*, the additional feature "*the first moving unit (4) and the second moving unit (5) both are connected to a distal surface of the carrier body (2)*" and the definition of the means for activation being amended to involve the needle hub in addition to the carrier body.

The parties disagree on whether these amendments are supported by the original application.

- 4.2 The additional feature that the first and second moving units are both connected to a distal surface of the carrier body is not disclosed as such in the original

application. It is only to be found in original claim 6 and on page 5, lines 1-2 of the original description - albeit with the terms "spring unit" being used instead of "moving unit" - hence, only for an inserter comprising the features defined in claim 5, on which claim 6 depends, and described with the same language in the description on page 4, lines 19-31. An example of this inserter is further described on page 6, line 11 of the original description with reference to the figures. This has not been disputed by the appellant.

This inserter is spring-actuated and relies on a very specific interaction between the first and second spring units, the housing, the carrier body and the needle hub that, upon activation, enables the inserter to be actuated to ensure the automatic insertion and retraction of the insertion needle. For this purpose, this interaction requires a particular coupling between these components, namely, as defined in claim 5, requiring at least that:

- (a) *the first and second spring units be respectively biasing the carrier body and the housing, on one side, and the carrier body and the needle hub, on the other side*

- (b) *in the retracted position before insertion, the carrier body and the needle hub are locked to each other*

In further stipulating that the first and second spring units are both connected to a distal surface of the carrier body, claim 6 limits the spring-actuated mechanism defined in claim 5. The Board thus shares the

respondent's view that the feature of claim 6 is inextricably linked with features (a) and (b).

Thus, contrary to the appellant's argument, the feature of claim 6, even generalised to relate to "moving unit[s]" instead of "spring unit[s]", cannot be isolated from features (a) and (b) without adding subject-matter extending beyond the original disclosure. It follows that claim 1 of the main request, which fails to define features (a) and (b), is based on an intermediate generalisation of the spring-actuated inserter unallowable under Article 123(2) EPC.

This conclusion applies even if it is assumed that, as argued by the appellant, the inserter of claim 5 is an example of a more general inserter described in broader terms in the original description from page 3, line 30 to page 4, line 17 and claimed in original claim 1.

- 4.3 Moreover, the original application does not disclose *"means for activation which should be activated at least once in order to bring the carrier body (2) and the needle hub (3) from a retracted to a forward position, and the needle hub (3) back from the forward to the retracted position"* either.

The appellant pointed to claims 1 and 2 and page 4, lines 7-9 of the description of the original application, arguing that these passages contained an error that the person skilled in the art would obviously recognise and correct.

However, this argument is not convincing. These passages, which consistently refer to the sole carrier body being moved between the retracted and forward positions, do not contain any contradiction or

technically nonsensical matter. Hence, as put forward by the respondent, the person skilled in the art has no reason to suspect any error in these passages.

Rather, the person skilled in the art understands from page 9, lines 15-27 of the original description that the spring-actuated inserter is "activated by the user by unlocking the carrier body 2 from the housing 1". While this unlocking is explicitly not limited to the mechanism disclosed in this passage, the original application does not provide support for means for activation of the spring-actuated inserter which would not be based on the unlocking of the carrier body from the housing.

Hence, claim 1 of the main request, which generally defines means for activation but omits the following feature of

(c) the inserter being activated by unlocking the carrier body from the housing

is based on a further intermediate generalisation of the spring-actuated inserter unallowable under Article 123(2) EPC.

5. Auxiliary request 1 - added subject-matter

Claim 1 of auxiliary request 1 infringes Article 123(2) EPC for the same reasons as discussed in point 4.3 above for the main request.

6. Admittance of auxiliary request 2

Auxiliary request 2 is identical to the second auxiliary request on which the decision under appeal

was based. As put forward by the respondent, the second auxiliary request was filed by the appellant during the first oral proceedings before the Opposition Division. The request was admitted by the Opposition Division in the exercise of its discretion (point 11 of the decision), and the impugned decision is based on this request (points 12 to 40).

In accordance with the established case law, the boards should overrule the way in which a department of first instance exercised its discretion in reaching a decision only if the board concludes that it did so in accordance with the wrong principles, without taking the right principles into account, or in an arbitrary or unreasonable way, thus exceeding the proper limits of its discretion.

In the current case, the Board sees no reason to doubt that the Opposition Division, in admitting the second auxiliary request, exercised its discretion reasonably. For this reason, the Board decided to consider auxiliary request 2.

7. Auxiliary request 2 - added subject-matter

7.1 As acknowledged by the respondent, claim 1 of auxiliary request 2 is directed to the spring-actuated inserter originally disclosed in claim 5 and described in detail in the description from page 6, line 12.

Compared to claim 1 of the main request, claim 1 of auxiliary request 2 explicitly defines features (a), (b) and (c) mentioned above. The objections under Article 123(2) EPC raised above against the main request have therefore been overcome.

7.2 Contrary to the respondent's view, the feature that the first compression spring is biasing the housing and the carrier body "for bringing the carrier body (2) and the needle hub (3) to the forward position" is explicitly disclosed in the original description on page 8, last paragraph. Similarly, the feature that the second compression spring is biasing the carrier body and the needle hub "for bringing the needle hub (3) to a retracted position" is disclosed on page 10, lines 10-11. This passage refers to "the position shown in fig. 4". The Board recognises that Figure 4 does not enable drawing any conclusion on the respective positions of the different components of the mechanism. However, the description on page 6, lines 23-25 explains that Figure 4 illustrates the retracted position of the needle hub.

7.3 The respondent also objected to several other features originally disclosed for the spring-actuated inserter, the omission of which also resulted, in its view, in unallowable intermediate generalisations.

This argument does not convince the Board because these features merely further specify some of the features already claimed in claim 1. The features described on page 8, line 11 to page 9, line 6 merely relate to one possible locking mechanism between the carrier body and the needle hub suitable for implementing feature (b) (page 8, lines 14-15: "*locking members 2a of the carrier body 2 and the protruding members 3a of the needle hub 3*"). The features described on page 9, lines 18-27 relate to one possible way of implementing feature (c).

7.4 The Board is also satisfied that the back references defined in the dependent claims of auxiliary request 2

do not result in claimed subject-matter extending beyond the original disclosure, contrary to the respondent's argument.

Claims 2-6 are based on original claims 7-11. The latter all depended directly or indirectly on original claim 5, the features of which are all included in independent claim 1. Contrary to the respondent's argument, the fact that claim 1 comprises further features in addition to those of original claim 5 (e.g. the feature of original claim 6) does not result in added subject-matter.

Claim 7 is based on original claim 13. It is true that original claim 13 recited an inserter "according to claims 1-12", thus including the features not only of claims 5 to 12, directed to the spring-actuated inserter, but also those of claims 1 to 4, directed to another inserter defined in more general terms. However, from the original description from page 4, line 19 to page 5, line 26, the person skilled in the art understands that the features of original claim 13 relate to the spring-actuated inserter only. Omitting the features of original claims 1 to 4 in claim 7 of auxiliary request 2 thus does not add subject-matter extending beyond the original disclosure.

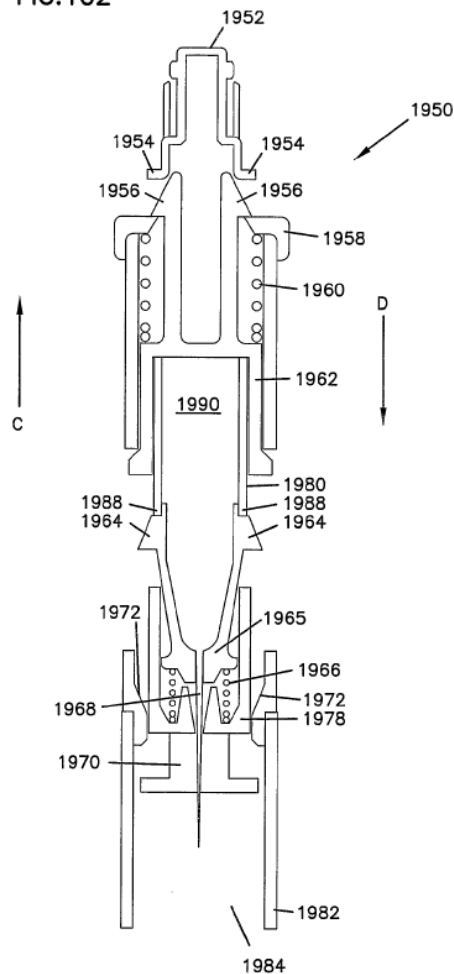
More generally, the person skilled in the art understands from this passage of the original description that the additional features defined in dependent claims 2-7 of auxiliary request 2 are all optional features of the spring-actuated inserter to which claim 1 is directed.

7.5 It follows that the claims of auxiliary request 2 do not include added subject-matter. The requirements of Article 123(2) EPC are therefore met.

8. Auxiliary request 2 - novelty in view of E1

8.1 It is common ground that E1 discloses in Figures 97 to 102 an inserter 1950 for an infusion set comprising, *inter alia*, a housing 1958, 1982; a needle hub 1965; a first compression spring 1960; a second compression spring 1966 and a retainer body 1978 carrying an infusion part 1970. Figure 102, reproduced below, illustrates the configuration of the inserter ready for insertion (page 26, lines 28-29).

FIG.102



A point of dispute between the parties is whether this inserter anticipates features (b) and (c), namely:

(b) *in the retracted position before insertion, the carrier body and the needle hub are locked to each other*

(c) *the inserter being activated by unlocking the carrier body from the housing*

8.2 The parties considered two interpretations of this inserter: the claimed carrier body was formed in E1 either by (i) the retainer body 1978 alone or (ii) the retainer body 1978 in combination with the lock member 1962 and the main body 1980.

As argued by the appellant, the lock member 1962, the main body 1980 and the retainer body 1978 are consistently described in the description of E1 as distinct entities. In Figure 102, the retainer body 1978 and the main body 1980 are depicted as separate parts with the needle hub 1965 being arranged in between, and there is no disclosure in the description of an element not visible in the figure that would connect the retainer body 1978 with the main body 1980.

Moreover, the fact that the lock member 1962, the main body 1980 and the retainer body 1978 move forwards in combination during the insertion phase (page 27, lines 2-3) does not necessarily mean that these parts form in combination a single "body".

Furthermore, Figure 102 only shows the final configuration of the inserter after the lock member 1962 has been moved backwards (page 26, lines 24-29).

However, the description is silent about the respective movements of main body 1980 and retainer body 1978 during the retraction of the lock member. In addition, while the existence of some interaction between the various parts must be implicitly assumed to explain why the illustrated configuration is stable, this configuration could equally result from a tight-fit or friction engagement between the various components or from some bias exerted by the second spring 1966.

The Board thus concurs with the appellant's view that the person skilled in the art would not regard the lock member 1962, the main body 1980 and the retainer body 1978 as together forming a "carrier body".

It follows that the respondent's line of argument based on this interpretation fails at least for this reason.

In the following, the retainer body 1978 alone is therefore identified as the carrier body in accordance with the respondent's other line of argument.

8.3 Both features (b) and (c) require a "lock" between two mechanical parts (carrier body and needle hub for feature (b); carrier body and housing for feature (c)) in the configuration before activation.

In the context of the invention of the contested patent, the definition of a "lock" put forward by the appellant convinces the Board. This definition requires, for two parts to be "locked" to each other, that they are shaped specifically and mutually engage such that they are fastened or secured to each other, where for "unlocking" at least one part must deform to allow the parts to disengage and thus become "unlocked". Thus, contrary to the respondent's view, a

"lock" according to this definition differs from a mere tight-fit or friction engagement.

This definition is also the definition used in the contested patent. While the figures of the patent are of little value due to their low contrast, the Board notes that the description discloses in paragraphs [0029] and [0030] "protruding members" that "interlock[]" with corresponding "locking members" to lock the carrier body with the needle hub where the protruding members must be pushed inwardly - hence deformed - to become released from interlocking with the locking members (last sentence of paragraph [0029] and first sentence of paragraph [0030]). A similar lock mechanism is disclosed in paragraph [0033] for locking and unlocking the carrier body and the housing to and from each other.

The same definition is adopted in E1 for the lock member 1962 being initially locked to the housing 1958 via deformable barbs 1956 in the inserter of Figure 102, as well as for the embodiment of Figure 42 to which the appellant referred.

8.4 From similar considerations to in point 8.2 above, it follows that E1 does not directly and unambiguously disclose that the lock member 1962, the main body 1980, the needle hub 1965 and the retainer body 1978 are fastened to each other in the configuration shown in Figure 102.

8.4.1 As argued by the appellant, the retainer body 1978 and the needle hub 1965 are merely shown as abutting each other in Figure 102. Separating them from each other would require only a simple longitudinal relative

movement, possibly to overcome some friction or the bias of the second spring 1966, but no deformation.

It follows that E1 does not directly and unambiguously disclose that in the configuration shown in Figure 102 the retainer body 1978 and the needle hub 1965 are "locked" to each other, i.e. feature (b).

- 8.4.2 Moreover, even if in the configuration of Figure 102 the lock member 1962 and the housing 1958 are locked to each other via barbs 1956, this lock does not result in the retainer body 1978 itself being - indirectly - "locked" to the housing as asserted by the respondent.

The Board further notes that no direct lock between the retainer body 1978 and the housing is visible in Figure 102 either, in which these parts are also merely shown as contacting each other.

Consequently, E1 does not disclose feature (c) either, contrary to the respondent's argument.

- 8.5 The Board therefore concludes that the subject-matter of claim 1 of auxiliary request 2 is novel over E1.

9. Auxiliary request 2 - inventive step starting from E1

- 9.1 The subject-matter of claim 1 of auxiliary request 2 thus differs from the inserter disclosed in Figure 102 of E1 at least on account of features (b) and (c).

- 9.2 Both parties agreed that the objective technical problem to be solved starting from E1 could be formulated as to make the inserter at least more secure.

9.3 Contrary to the respondent's view, the person skilled in the art proceeding from E1 and facing this technical problem would not have included features (b) and (c) in the inserter of E1 without hindsight.

As the appellant argued, this would have significantly complicated the internal design of the inserter and required substantial modifications of the various parts forming its automatic insertion and retraction mechanism.

Moreover, including a further activation mechanism based on unlocking the carrier body from the housing in addition to the activation mechanism already present on the top of the inserter (based on cap 1952) would have been detrimental to the usability of the inserter. Notably, this would have required it to be used with two hands, something E1 explicitly describes as complicated and aims to avoid (page 1, lines 19-21; page 2, lines 4-6).

9.4 As argued by the appellant, the person skilled in the art would instead have considered other solutions to make the inserter more secure, for example, by adding a protective cap or using more suitable materials.

9.5 The Board thus concurs with the appellant's view that the person skilled in the art proceeding from E1 would not have arrived at the subject-matter of claim 1 in an obvious way and without hindsight. It follows that the subject-matter of claim 1 of auxiliary request 2 involves an inventive step over E1.

10. Auxiliary request 2 - further objections filed in writing

The further objections against auxiliary request 2 raised by the respondent in its written submissions do not convince the Board.

10.1 *Extension of scope of protection*

According to claim 1, the first compression spring is biasing the housing and the carrier body "for bringing the carrier body (2) and the needle hub (3) to the forward position". It is clear from this wording that it is the compression spring which causes the carrier body and the needle hub to be brought forward, thus to be "moved" (see point 7.2 above). The same applies to the second compression spring defined in claim 1. The compression springs as defined in claim 1 therefore both represent limitations of the "moving units" defined in claim 1 as granted, contrary to the respondent's argument.

The respondent also objected to the feature of claim 1 of "the inserter being activated by unlocking the carrier body (2) from the housing". While this feature explicitly defines the action by which the claimed inserter is to be activated, it leaves open which part of the inserter is to be activated by the user to achieve this action. This unspecified part constitutes nothing other than "means for activation" which should be activated at least once to activate the inserter. The sentence "whereby upon activation (...) to the retracted position" that follows the objected to feature in claim 1 stipulates that upon activation, the carrier body and the needle hub are brought from the retracted to the forward position, and then the needle hub is brought back from the forward to the retracted position. Hence, contrary to the respondent's argument, the feature objected to above does implicitly define

"means for activation" like those defined in claim 1 as granted. These "means for activation" are, however, more limited than in claim 1 as granted since they are based on the action of unlocking the carrier body from the housing.

Accordingly, the scope of protection of granted claim 1 has not been extended by these amendments, as required by Article 123(3) EPC.

10.2 *Clarity*

10.2.1 The expression "the compression spring is biasing feature A and feature B" clearly means that the spring exerts a compressive bias on both features A and B to push them apart, so that these features would move away from each other if they were not prevented from doing so by some lock provided elsewhere in the mechanism. As discussed in point 10.1 above, it is clear that it is this bias which, after activation of the inserter, causes the movement of various parts defined by the "for bringing (...) to" wording.

The other interpretations suggested by the respondent are not technically sensible and fail to take into account the other features of claim 1.

10.2.2 While the orientation or shape of the guiding means is not specified in claim 1, it is clearly derivable from claim 1 that they should guide the movement of the carrier body during its movement from its retracted position to the forward position, this being the sole movement of the carrier body defined in claim 1.

10.2.3 The expression "for piercing of the skin" merely defines the suitability of the insertion needle for piercing the skin of the patient.

10.2.4 The Board is therefore satisfied that claim 1 is clear.

10.3 *Insufficiency of disclosure*

The Board shares the respondent's view that the figures of the patent, of poor quality, contain little exploitable information, if any.

The Board is nevertheless satisfied that the description discloses the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. A person skilled in the art could also use their common general knowledge to supplement the information contained in the patent.

The Board is convinced that the person skilled in the art would have no difficulty or undue burden in building a carrier body carrying an infusion part or guiding means to guide the movement of the carrier body, contrary to the respondent's contention.

10.4 *Exception to patentability*

The exception to patentability under Article 53(c) EPC applies to methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body. This provision does not apply to products for use in any of these methods.

The claims of auxiliary request 2 are directed to an inserter, hence to a product. As indicated in point

10.2.3 above, the expression "for piercing of the skin" merely indicates the suitability of the needle for piercing the patient's skin. In no way can the subject-matter of claim 1 be interpreted as a method.

It follows that auxiliary request 2 does not contain subject-matter falling under the exclusion of Article 53(c) EPC.

10.5 *Industrial applicability*

The Board has no doubt that the claimed inserter, being a medical instrument for inserting an infusion part of an infusion set into a patient, who is not part of the claimed device, is susceptible of industrial application.

The presence of the expression "for piercing of the skin" is irrelevant.

10.6 *Further novelty objections*

10.6.1 Regarding the novelty objection in view of E3, Figures 13-15, the respondent identified the compression spring 31 as both the first and second compression spring. However, claim 1 clearly requires two distinct compression springs. This objection is therefore not persuasive.

10.6.2 The other novelty objections raised by the respondent are based on alternative interpretations of the expression "the compression spring is biasing feature A and feature B", namely that it could also mean that the spring biased both features A and B against a further, unspecified feature C, or that the spring biased one of these features towards the other.

However, this expression is to be interpreted in the context of the contested patent as explained in point 10.2.1 above. The other interpretations suggested by the respondent are, in the Board's view, not technically sensible given the context and fail to take into account the whole disclosure of the patent.

For this reason alone, these other novelty objections fail to convince the Board.

10.7 *Further inventive-step objections*

10.7.1 The objections starting from E4, Figures 10A-10D as well as from E9, E10 and E13 are also based on alternative interpretations of the expression "is biasing", which the Board does not find technically sensible as explained in point 10.6.2 above. Therefore, these objections also fail to convince the Board.

10.7.2 Starting from the other known inserters cited by the respondent, substantial modifications would have been required to arrive at the subject-matter of claim 1. These modifications are, in the Board's view, well beyond the modifications that the person skilled in the art would have considered without hindsight and without exercising an inventive step.

The Board thus concludes that the subject-matter of claim 1 of auxiliary request 2 also involves an inventive step over these documents.

11. **Conclusion**

From the above considerations, it follows that none of the objections raised by the respondent prejudices the

maintenance of the contested patent on the basis of the claims of the appellant's auxiliary request 2.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the Opposition Division with the order to maintain the patent with the following claims and a description to be adapted thereto:

Claims 1-7 of auxiliary request 2 filed with the statement of grounds of appeal

The Registrar:

The Chair:



D. Hampe

M. Alvazzi Delfrate

Decision electronically authenticated