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Datasheet for the decision of 4 June 2025

Case Number: T 0818/23 - 3.2.02

Application Number: 07704923.7

Publication Number: 1998831

IPC: A61M5/20, A61M5/31, A61M5/32

Language of the proceedings: EN

Title of invention:
IMPROVED AUTOINJECTOR SUPPORTING THE SYRINGE AT THE FRONT

Patent Proprietor:
SHL Medical AG

Opponents:
SHL Medical AG
Eisenführ Speiser

Headword:

Relevant legal provisions:
EPC Art. 123(2)
RPBA 2020 Art. 12(4)

This datasheet is not part of the Decision
It can be changed at any time and without notice

Keyword:
Amendments - intermediate generalisation - allowable (no)
Amendment to case - amendment overcomes objection (no) - amendment admitted (no)
- amendment admitted (no)

Decisions cited:
G 0002/10, T 2133/19

Catchword:

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Boards of Appeal

Chambres de recours

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Case Number: T 0818/23 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 4 June 2025

Appellant: (Patent Proprietor)	SHL Medical AG Gubelstrasse 22 6300 Zug (CH)
Representative:	Bardehle Pagenberg Partnerschaft mbB Patentanwälte Rechtsanwälte Prinzregentenplatz 7 81675 München (DE)
Respondent: (Opponent 1)	SHL Medical AG Gubelstrasse 22 6300 Zug (CH)
Representative:	Vossius & Partner Patentanwälte Rechtsanwälte mbB Siebertstraße 3 81675 München (DE)
Respondent: (Opponent 2)	Eisenführ Speiser Patentanwälte Rechtsanwälte PartGmbB Johannes-Brahms-Platz 1 20355 Hamburg (DE)
Representative:	Eisenführ Speiser Patentanwälte Rechtsanwälte PartGmbB Johannes-Brahms-Platz 1 20355 Hamburg (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 2 March 2023 concerning the maintenance of European Patent No. 1998831 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 appealed against the Opposition Division's decision that, account being taken of the amendments made by the patent proprietor during the opposition proceedings in accordance with auxiliary request 1, the patent and the invention to which it related met the requirements of the EPC. The Opposition Division found that the patent could not be maintained as granted due to added-subject-matter.

II. The Board summoned the parties to oral proceedings and sent its preliminary opinion.

III. Oral proceedings took place on 4 June 2025.

The appellant requested that the patent be maintained as granted (main request) or, alternatively, on the basis of one of auxiliary requests 0a to 0g, filed with the statement of grounds of appeal on 12 July 2023, auxiliary requests 1 to 3, filed on 8 November 2022, auxiliary request 4, filed on 13 January 2023, and auxiliary request 5, filed on 8 November 2022.

The respondent requested that the appeal be dismissed.

IV. **Claim 1 of the main request** reads as follows:

"An autoinjector comprising a housing in which can be mounted a syringe comprising:

a barrel for holding a volume of medicament,
a needle (10) at one end of the barrel in fluid communication with the medicament,

a plunger axially-moveable in the barrel to a forwardmost position;
a needle sheath (16) which is capable of sealing the forwardmost end of the needle to maintain sterility of the medicament within the barrel whereby, in use, the needle sheath must be removed from the needle immediately prior to actuating the autoinjector; and
a removable needle cover (17) for containing the needle sheath (16);
the autoinjector comprising:

a syringe support means (100, 100')for supporting the barrel of the syringe at an axial location at or forward of the forwardmost position of the plunger of the syringe, the syringe support means (100, 100') providing a reaction surface (109, 109') for a front shoulder of the barrel or a narrowed cone region of the syringe where the needle is attached;
characterised in that said syringe support means (100, 100') comprises an intermediate portion (105) and a front portion which together include radially spaced slots (107) that define a plurality of radially flexible fingers (108, 108'), the plurality of radially flexible fingers (108, 108') comprising one or more inwardly-directed protrusions which form said reaction surface, wherein the reaction surface (109, 109') is configured to provide an axial compressive force on the barrel of the syringe when a forward axial force is applied to the plunger of the syringe, and wherein when the syringe is inserted into

the syringe support means (100, 100'), the radially flexible fingers (108, 108') flex radially outward from a normal position as a needle cover (17) passes and then spring back to their normal position."

Claim 1 of auxiliary request 0a reads as claim 1 of the main request except that the reference signs "100'", "108'" and "109'" have been deleted and that the expression "inwardly-directed protrusions which form" has been replaced by the expression:

"inwardly-directed protrusions provided on the interior of the plurality of the radially flexible fingers, said one or more inwardly-directed protrusions forming"

Claim 1 of auxiliary request 0b reads as claim 1 of auxiliary request 0a except that the following wording has been inserted after the first occurrence of the expression "radially flexible fingers (108)":

", wherein the front portion is of narrower diameter than the intermediate portion"

Claim 1 of auxiliary request 0c reads as claim 1 of auxiliary request 0a except that the following wording has been inserted after the third occurrence of the expression "radially flexible fingers":

"in the intermediate portion (105)"

Claim 1 of auxiliary request 0d reads as claim 1 of auxiliary request 0b except that the following wording has been inserted after the third occurrence of the expression "radially flexible fingers":

"in the intermediate portion (105)"

Claim 1 of auxiliary request 0e reads as claim 1 of auxiliary request 0a except that the following wording has been inserted after the first occurrence of the expression "radially flexible fingers (108)":

"having free ends extending in a rearward direction"

Claim 1 of auxiliary request 0f reads as claim 1 of auxiliary request 0e except that the following wording has been inserted after the third occurrence of the expression "radially flexible fingers":

"in the intermediate portion (105)"

Claim 1 of auxiliary request 0g reads as claim 1 of auxiliary request 0a except that the following wording has been inserted after the first occurrence of the expression "radially flexible fingers (108)":

"having free ends extending in a rearward direction, wherein the front portion is of narrower diameter that the intermediate portion"

Claim 1 of auxiliary request 1 reads as claim 1 of the main request except that the following wording has been inserted after the expression "front portion":

"of narrower diameter than the intermediate portion"

Claim 1 of auxiliary request 2 reads as claim 1 of the main request except that the expression "and then spring back to their normal position" has been replaced by the expression:

"to create sufficient diameter for the needle cover (17) to pass the inwardly-directed protrusions, without exerting excessive force on the needle therein, and then spring back to their normal position once the needle cover has passed"

Claim 1 of auxiliary request 3 reads as claim 1 of the main request except that the following wording has been inserted at the end of the claim:

", and said syringe support means (100, 100') comprises a spring retainer (111) made from steel, metal or another material which does not significantly lose its resilience over time and having elongate fingers which cooperate with the flexible fingers (108, 108') so as to urge them radially-inwardly"

Claim 1 of auxiliary request 4 reads as claim 1 of the main request except that the following wording has been inserted at the end of the claim:

", and wherein an internal diameter between said inwardly-directed protrusions is smaller than the exterior diameter of the syringe barrel, and wherein, when the device is fully assembled ready for use, said inwardly-directed protrusions are axially located between a needle cover (17) and the front shoulder (92) of the syringe barrel"

Claim 1 of auxiliary request 5 reads as claim 1 of the main request except that the following wording has been inserted at the end of the claim:

", and wherein said syringe support means (100, 100') further comprises one or more alignment tags (110, 110') at the front end thereof, the autoinjector

further comprising a front housing (200) having a bore (201) therethrough, the interior surface of the bore being provided with one or more longitudinal slots (202), positioned so that said alignment tags (110, 100') are locateable therein, when said front housing (200) and syringe support means (100, 100') are assembled together"

V. The appellant's arguments relevant to this decision can be summarised as follows.

Main request - added subject-matter

The Opposition Division had wrongly come to the conclusion that the omission of the following features in claim 1 of the main request constituted an unallowable intermediate generalisation:

(a) the free ends of the fingers extending in a rearward direction
(b) the protrusions being provided only on the intermediate portion
(c) the protrusions being on the interior of the fingers
(d) the front portion having a narrower diameter than the intermediate portion

The invention as disclosed in the application as filed was an autoinjector having radially-flexible fingers with inwardly-directed protrusions that defined a reaction surface to apply an axial compressive force on the syringe barrel during injection. This core technical teaching was preserved in claim 1 of the main request, and thus the criterion of the gold standard as referred to in G 2/10 was fulfilled. It was neither described in nor apparent from the application as filed

how the omitted features contributed to the necessary elasticity for the radial expansion and springing back of the radially-flexible fingers.

The Opposition Division had stated that the only embodiment covered by the claim comprised a syringe support means as depicted in Figures 7 to 11 of the patent.

In the application as filed, with reference to this embodiment, the radially-flexible fingers had been described together with radially-spaced slots. However, the fact that the free ends of the radially-flexible fingers extended in a rearward direction had not been described at all. The only passage which referred to free ends of radially-flexible fingers extending in the rearward direction was on page 16, lines 29 to 31, which related to a different embodiment. If this further embodiment had not been disclosed, the issue of an unallowable intermediate generalisation would not have arisen. Moreover, the fact that this further embodiment in the application as filed (Figures 17 to 20) comprised fingers extending in the forward direction taught that the orientation of extension was interchangeable and did not affect the ability to grip the syringe barrel. The key function of the radially-flexible fingers was their radial flexibility, not the direction in which they extended (rearward or forward). Although Figures 7 to 9 showed that the free ends of the fingers extended in a rearward direction, this was insufficient for providing an inextricable functional link with the other claimed features, absent express disclosure in the description that this was the only viable configuration for this embodiment. This conclusion had also been reached in other cases, such as T 2133/19, in similar situations, where at least one

section of the original disclosure disclosed features added to an original claim without any immediate link to allegedly omitted features.

According to the application as filed, the inwardly-directed protrusions were intended to form the reaction surface, i.e. the surface which abutted the syringe fitted into the syringe support means, providing axial support. Page 13, lines 16 to 35 of the application as filed taught that the reaction surface should be located "at a desired axial location". This meant that the protrusions did not have to be on the intermediate portion but could be elsewhere as long as they could provide the reaction surface as claimed. The embodiment shown in Figures 17 to 20 of the application as filed had protrusions in the front portion, for example.

Claim 1 of the main request specified that the protrusion were "inwardly-directed". Thus, it was implicit that they were located on the interior of the fingers. Even inwardly-directed protrusions at the distal end of the fingers would still be on the interior of the fingers, which, themselves, would be prolonged by the protrusions. In any case, protrusions at the finger ends, as described for the embodiment of Figures 17 to 20, would still provide the required axial support. Hence, protrusions being defined on the interior of the fingers were not structurally essential according to the application as filed.

The relative diameter of the front and intermediate portion of the syringe support means, which referred to the exterior diameter as shown in Figures 7 to 11, was not functionally linked to the provision of the reaction surface either. Nor was it apparent how it would facilitate flexing of the fingers. The

application as filed contained several sections where the flexing of the fingers was disclosed without defining any relative diameters. To the contrary, the application taught that the flexibility of the fingers relied on the material rather than on relative diameters of front portions and intermediate portions (page 17, lines 9 to 12).

Auxiliary requests - admittance

Auxiliary requests 0a to 0g had been submitted with the statement of grounds of appeal and were subject to the provisions of Article 12(4) RPBA. A reasonable application of this article supported their admittance as the amendments over the main request were straightforward and constituted attempts to overcome the objections raised by the respondent. Auxiliary requests 1 to 5 corresponded to auxiliary requests 2 to 6 before the Opposition Division, which had been renumbered in this way for procedural economy. Although they were not the subject of the decision under appeal, a reasonable approach had to take the principle of procedural economy into account at both instances.

The appellant conceded in the oral proceedings that none of the auxiliary requests comprised all features (a) to (d) identified above.

VI. The respondent's arguments relevant to this decision can be summarised as follows.

Main request - added subject-matter

Compared to claim 1 of the application as filed, claim 1 of the main request had been amended by the addition of features from the description, including

that intermediate and front portions of the syringe support means together comprised radially-spaced slots that defined the radially-flexible fingers and that the radially-flexible fingers flexed radially outward from a normal position as a needle cover passed and then sprung back to their normal position. These features were not concerned with the general problem of reducing the risk of breakage of a glass barrel during injection because this would be achieved by any gripping means that held the barrel under compression. The added features aimed at obtaining an easier assembly process and, for this purpose, had been disclosed in combination with features (a) to (d) identified above in one embodiment of the application as filed, the syringe support of which was depicted in Figures 7 to 11.

Figures 7 to 11, page 15, lines 1 to 3 and page 16, lines 29 to 31 of the application as filed clearly disclosed that the free ends of the fingers extended in a rearward direction. The feature that intermediate and front portions together included the radially-spaced slots was structurally and functionally linked with the feature that the fingers extended in a rearward direction. If the fingers extended forwardly, it would not be possible for the intermediate and front portions together to comprise the slots because outer flexion of the front of the fingers would be prevented.

There was no disclosure in the application as filed of the protrusions being provided on the front portion instead of the intermediate portion. In the embodiment of Figures 7 to 9 of the application as filed, if the protrusions were provided on the front portion, the fingers would be unable to flex.

Protrusions being inwardly-directed was not equivalent to the protrusions being on the interior of the fingers. With the omission of the feature of the protrusions being on the interior of the fingers, claim 1 of the main request could be read such that the protrusions, to create the reaction surface, could be located at the distal end of the fingers as inwardly orientated extensions of the fingers. Such a configuration was not disclosed in the embodiment of Figures 7 to 9 of the application as filed and would cause this embodiment not to work.

The syringe support means comprising an intermediate portion and a front portion which together include radially-spaced slots defining radially-flexible fingers was only disclosed for the embodiment of Figures 7 to 9 of the application as filed, in which the front portion was of a narrower diameter than the intermediate portion (page 12, lines 29 to 30). All these features were structurally and functionally linked because this meant that the front portion could flex such that the rest of the fingers could flex sufficiently radially outwardly.

Auxiliary requests - admittance

The admittance of all the auxiliary requests was at the Board's discretion. Among other reasons, these requests should not be admitted because they did not overcome, *prima facie*, the objections of added subject-matter.

Reasons for the Decision

1. Subject-matter of the patent

The claimed invention is an autoinjector comprising a housing in which a syringe can be mounted.

An autoinjector is an automatic injection device designed to facilitate automated self-delivery of a dose of medicament, for example, interferon, to a patient.

The syringe of the autoinjector comprises a barrel for holding a volume of medicament, a needle at one end of the barrel in fluid communication with the medicament, a plunger axially movable in the barrel to a forwardmost position, a needle sheath which is capable of sealing the forwardmost end of the needle and a removable needle cover for containing the needle sheath. These are typical components of a conventional syringe.

The claimed autoinjector comprises a syringe support means for supporting the barrel of the syringe at an axial location at or forward of the forwardmost position of the plunger of the syringe. The patent discloses such a support means, intended to be placed within a housing of the autoinjector, with reference to its Figures 7 and 8, reproduced below.

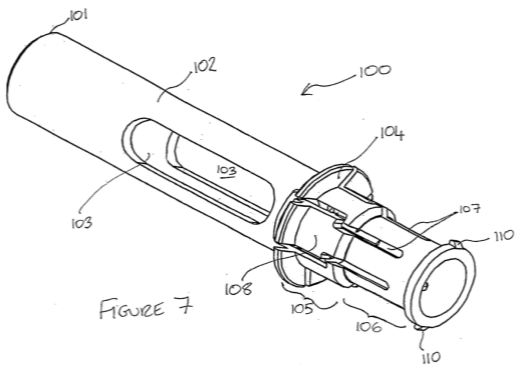

FIGURE 7

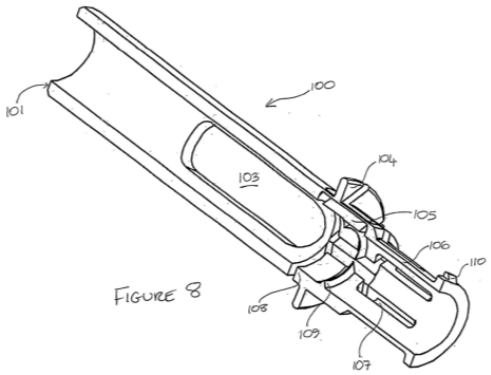

FIGURE 8

The syringe support means (100) provides a reaction surface (109) for a front shoulder of the barrel or a narrowed cone region of the syringe where the needle is attached and comprises an intermediate portion (105) and a front portion (106).

The intermediate portion and the front portion, together, include radially-spaced slots (107) that define a plurality of radially-flexible fingers (108) comprising one or more inwardly-directed protrusions (109) which form the reaction surface.

The reaction surface is configured to provide an axial compressive force on the barrel of the syringe when a forward axial force is applied to the plunger of the syringe.

When the syringe is inserted into the syringe support means, the radially-flexible fingers flex radially outward from a normal position as a needle cover passes and then spring back to their normal position.

With the claimed syringe support means, the use of a conventional syringe with the autoinjector is made possible.

2. Main request - added subject-matter

2.1 As the appellant also submitted, the subject-matter of claim 1 of the main request is derived from claims 1, 6, 12 and 13 of the application as filed, with the addition of the features of the intermediate and front portions of the syringe support means including, together, radially-spaced slots that define radially-flexible fingers, and of the radially-flexible fingers configured to, when the syringe is inserted into the syringe support means, flex radially outward from a normal position as the needle cover passes and then spring back to their normal position. These added features are disclosed in the embodiment of the autoinjector with a syringe support means as shown in Figures 7 to 11 of the application as filed.

The Opposition Division considered that claim 1 of the main request comprised an unallowable intermediate generalisation of this embodiment of the application as filed.

The Board agrees with the Opposition Division and concludes that the omission of the following features of this embodiment presents the person skilled in the art with technical information not directly and unambiguously derivable from the application as filed:

(a) the free ends of fingers extending rearwardly
(b) the protrusions being provided only on the intermediate portion
(c) the protrusions being on the interior of the fingers
(d) the front portion having a narrower diameter than the intermediate portion

2.2 The syringe support means shown in Figures 7 to 11 of the application as filed comprises a mechanical arrangement of interacting features. These interacting features, which comprise the features added to the claim, allow the axial insertion of the syringe from the proximal end of the support, the radial expansion of the flexible fingers of the support as the needle cover passes and the springing back of these fingers to provide a suitable reaction surface for the syringe when the autoinjector is actuated. The omitted features (a) to (d) cooperate with the intermediate and front portions of the syringe support means including, together, radially-spaced slots that define radially-flexible fingers and make it possible that the radially-flexible fingers flex radially outwardly and spring back to their normal position to provide an effective reaction surface as the syringe is inserted. As is explained in more detail below, for the person skilled in the art, all the omitted features are technically necessary in the embodiment with the syringe support means of Figures 7 to 11 of the application as filed to cooperate with the features added to the claim and provide the required elasticity of the fingers and a reaction surface at an appropriate axial position and which could reliably withstand the forward axial force applied to the plunger of the syringe for expelling medicament. They are thus inextricably linked with the features added to the claim. It is irrelevant whether this technical information is explicitly described in the application as filed as long as the disclosure as a whole conveys it in a direct and unambiguous way. A claim without these features teaches that the effect to be achieved by the features added to the claim can be obtained without the cooperation of features (a) to (d). This is in contrast to, and thus extends beyond, the content of

the application as filed. This, in turn, does not satisfy the criterion of the gold standard in accordance with G 2/10, referred to by the appellant.

The appellant's argument that the core technical teaching of the application as filed was that the fingers should provide a reaction surface is not convincing as the features added to claim 1 of the main request from the embodiment having a syringe support means as shown in Figures 7 to 11 more specifically relate to the possibility of mounting the syringe with a needle cover going past the fingers and having the fingers expand and spring back.

2.3 In the embodiment of the syringe support means shown in Figures 7 to 11, due to the presence of the front and the intermediate portions including, together, radially-spaced slots, for the person skilled in the art, the extension of the fingers in a rearward direction contributes to the provision of the necessary elasticity while permitting the reaction surface to be in a suitable position. Without further substantial modifications of the embodiment, fingers extending in a forward direction, into the front portion, would either be too stiff or would leave no room for a reaction surface located at a distance from the distal end of the support sufficient to house the needle cover as shown.

The appellant's argument that the free ends of the fingers extending in a rearward direction was not described with reference to the syringe support means of Figures 7 to 11 is not convincing. Page 16, lines 29 to 31 of the application as filed read:

"*in the Figure 17 embodiment of the syringe holder*

100', the radially-flexible fingers 108' have their free ends extending in the forward direction (compare with the radially-flexible fingers 108 in Figure 8 which have their free ends extending in the rearward direction)."

It is irrelevant that this passage is found in a part of the application which mainly describes the embodiment of Figures 17 to 20 since its disclosure also concerns the syringe support means of Figures 7 to 11.

Moreover, the free ends of the fingers extending in a rearward direction are clearly shown in Figures 7 to 9. This renders moot even the appellant's hypothetical argument that if the embodiment of Figures 17 to 20 had not been disclosed, the issue of an unallowable intermediate generalisation would not have arisen.

Whether the embodiment of Figures 17 to 20 shows free ends of the fingers extending forwardly is irrelevant as this embodiment comprises a completely different mechanical arrangement, which provides elasticity to the fingers due to the length of the slots in a proximal portion of the syringe support means. The reference to decision T 2133/19 is of no relevance since this decision relates to a different disclosure and, in the current case, there is an inextricable link between the fingers extending in a rearward direction and the claimed configuration of the front and the intermediate portions of the syringe support means.

2.4 The protrusions being provided on the intermediate portion also contributes, in the embodiment of the syringe support means shown in Figures 7 to 11, to the provision of the necessary elasticity while permitting

the reaction surface to be in a suitable position. Placing the protrusions on the front portion would render the fingers too stiff or leave no room for a reaction surface located at a distance from the distal end of the support sufficient to house the needle cover as shown. The "desired axial location" of the reaction surface as mentioned on page 13, lines 16 to 20 of the application as filed is to be understood in this context.

Again, whether the embodiment in Figures 17 to 20 shows protrusions on a front portion is irrelevant as this embodiment comprises a completely different mechanical arrangement.

2.5 As regards the protrusion being provided on the interior of the fingers, the application as filed distinguishes between such protrusions in the embodiment of the syringe support means of Figures 7 to 11 ("gripping means" on page 13, lines 10 to 12) and protrusions at the end of the fingers in the embodiment of Figures 17 to 20 ("gripping means" on page 16, lines 32 to 33). The appellant's argument that claim 1 of the main request already specified inwardly-directed protrusions is not convincing. Protrusions on the interior of the fingers are not the same as inwardly-directed protrusions, which could also be located at the end of the fingers.

Again, in the embodiment of the syringe support means shown in Figures 7 to 11, the provision of the protrusions on the interior of the fingers contributes to the necessary elasticity of the fingers while permitting the reaction surface to be in a suitable position. Protrusions at the end of the fingers would affect the stability and the desired position of the

reaction surface, in view of the presence of the needle cover.

What the embodiment in Figures 17 to 20 shows in respect of its protrusions is again irrelevant as this embodiment comprises a completely different mechanical arrangement.

2.6 The relative diameter of the front portion and the intermediate portion also contributes, in the eyes of the person skilled in the art, to the provision of the elasticity of the fingers together with the necessary structural stiffness of the support for withstanding the axial force applied through the piston. A thinner front portion, which is the result of a narrower (external) diameter, makes the fingers more flexible for a given axial length and permits the placement of the reaction surface at the desired axial location. There is no need for an explicit description for the person skilled in the art to understand this.

The passage on page 17, lines 9 to 12 referred to by the appellant concerns the embodiment of Figures 17 to 20 and the problem of plastic deformation during storage. This passage is irrelevant.

2.7 In conclusion, due to the omission of features (a) to (d) identified above, claim 1 of the main request provides the person skilled in the art with technical information which extends beyond the content of the application as filed. Hence, Article 123(2) EPC is not complied with, and the main request cannot be allowed.

3. Auxiliary requests - admittance

Auxiliary requests 0a to 0g were filed with the

statement of grounds of appeal. Auxiliary requests 1 to 5 were first filed before the Opposition Division. However, they did not have this rank in relation to the other claim requests considered in the decision under appeal. They were numbered auxiliary requests 2 to 6, so the Opposition Division not to decide on them since the then pending auxiliary request 1 was found allowable.

As also explained in the Board's preliminary opinion, which was not contested by the appellant, all of auxiliary requests 0a to 0g and 1 to 5 may be admitted only at the Board's discretion under Article 12(4) RPBA since they must be regarded as amendments of the appellant's case for the purposes of this article.

Under Article 12(4) RPBA, the Board must exercise its discretion in view of, *inter alia*, the suitability of the amendments to address the issues which led to the decision under appeal.

It is common ground that none of auxiliary requests 0a to 0g and 1 to 5 can successfully address the objection of added subject-matter detailed in the decision under appeal and found convincing by the Board since no claim 1 of these requests comprises all features (a) to (d) identified above.

For this reason, the Board decided not to admit any of auxiliary requests 0a to 0g and 1 to 5 under Article 12(4) RPBA.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

A. Chavinier-Tomsic M. Alvazzi Delfrate

Decision electronically authenticated