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Datasheet for the decision of 23 July 2021

Case Number:	T 1575/18 - 3.2.02
Application Number:	05783727.0
Publication Number:	1786491
IPC:	A61M5/24, A61M5/31, A61M5/20, A61M5/32
Language of the proceedings:	EN

Title of invention:
AUTOMATIC INJECTOR

Patent Proprietor:
Meridian Medical Technologies, Inc.

Opponents:
Merck Patent GmbH
ALK-ABELLO A/S

Headword:

Relevant legal provisions:
EPC Art. 100(c), 123(2)
RPBA Art. 13(2)

Keyword:
Grounds for opposition - added subject-matter (yes)
Late-filed argument - admitted (yes)
Late-filed auxiliary requests - justification for late filing (no) - admitted (no)

Decisions cited:
G 0001/93, T 0247/20

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

Boards of Appeal

Chambres de recours

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

Case Number: T 1575/18 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 23 July 2021

Appellant: (Patent Proprietor)	Meridian Medical Technologies, Inc. 6350 Stevens Forest Road, Suite 301 Columbia, MD 21046 (US)
Representative:	Lavoix 2, place d'Estienne d'Orves 75441 Paris Cedex 09 (FR)
Respondent: (Opponent 2)	Merck Patent GmbH Postfach Frankfurter Strasse 250 64293 Darmstadt (DE)
Representative:	Zacco Denmark A/S Arne Jacobsens Allé 15 2300 Copenhagen S (DK)
Respondent: (Opponent 3)	ALK-ABELLO A/S Böge Alle 6-8 2970 Hörsholm (DK)
Representative:	Sach, Greg Robert Sach & Associates Siedlungsstrasse 4a 85253 Erdweg (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 26 April 2018 revoking European patent No. 1786491 pursuant to Article 101(3)(b) EPC**

Composition of the Board:

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

Summary of Facts and Submissions

I. The patent proprietor has appealed against the Opposition Division's decision to revoke European patent No. 1 786 491 on the grounds of added subject-matter of all the requests.

II. The Board summoned the parties to oral proceedings.

III. By letter dated 6 July 2021 the respondent/opponent 2 announced that it would not be attending the oral proceedings.

IV. Oral proceedings took place on 23 July 2021 by videoconference. In accordance with Rule 115(2) EPC and Article 15(3) RPBA 2020, they were conducted without the respondent/opponent 2, who had requested in writing that the appeal be dismissed.

The appellant requested that the decision under appeal be set aside and that the patent be maintained as granted (main request) or on the basis of one of auxiliary requests 1 to 11, filed by letter dated 28 August 2018, and auxiliary request 12, filed during the oral proceedings.

The respondent/opponent 3 (hereinafter "the respondent") requested that the appeal be dismissed.

V. Claim 1 of the patent as granted (main request) reads as follows:

"An automatic injector (100) comprising:

a housing (110);

a cartridge container (140) disposed within the housing (110);
a cartridge (160) received within the cartridge container (140), the cartridge (160) having at least one opening (161) therein and containing a medicament, the medicament rearwardly confined by a plunger (438), wherein the cartridge (160) includes a needle assembly (163) to dispense the medicament there through, the needle assembly (163) including a needle (162);
an actuation assembly (130) providing a stored energy source capable of being released to drive the plunger (438) within the cartridge (160) to dispense the medicament through the needle assembly (163);
a needle cover (150) received within the housing (110), the needle cover (150) having a rear opening formed therein to permit the passage of the needle assembly (163) there through during a medicament dispensing operation, the needle cover (150) having a first locked position whereby the needle cover (150) is in a locked retracted position with respect to the housing (110) prior to activation of the auto-injector (100), the needle cover (150) having a second locked position whereby the needle cover (150) is in a locked extended position with respect to the housing (110) after operation of the auto-injector (100), the needle cover (150) having an end surface (152), the end surface (152) having an opening sized (152a) to permit passage of the needle (162) there through;
a first locking assembly that holds the needle cover (150) in the first locked position; and
a second locking assembly that holds the needle cover (150) in the second locked position;

wherein:
the auto-injector (100) is activated when the end surface (152) of the needle cover (150) is pressed against an injection site."

Claim 1 of auxiliary request 1 reads as claim 1 of the main request except that, after the second occurrence of "wherein", the claim reads as follows:

"the auto-injector (100) is activated when the end surface (152) of the needle cover (150) is pressed against an injection site, and
wherein the actuation assembly (130) comprises:
an outer body (230);
an inner body (330) operatively coupled to the outer body (230);
a collet (430) operatively coupled to the inner body (330); and
an energy source (530)."

Claim 1 of auxiliary request 2 reads as claim 1 of auxiliary request 1, with the following wording added at the end of the claim:

",
wherein the collet (430) has at least one tapered portion (434), and the outer body (230) of the actuation assembly (130) has at least one surface (239a) constructed and arranged to contact the at least one tapered portion (434), and
wherein the at least one surface (239a) is constructed and arranged to contact the at least one tapered portion (434) to compress the collet (430) in an area around the elongated opening (432) such that the collet (430) is released from

the inner body (330) in response to application of an activation force".

Claim 1 of auxiliary request 3 reads as claim 1 of the main request except that, after the second occurrence of "wherein", the claim reads as follows:

"the auto-injector (100) is activated when the end surface (152) of the needle cover (150) is pressed against an injection site,
wherein the actuation assembly (130) is mounted within the housing (110) adjacent an open end in the housing (110), and
wherein the auto-injector further comprises a release pin (120) removably attached to the actuation assembly (130) and the auto-injector (100) is not operable when the release pin (120) is connected to the actuation assembly (130)."

Claim 1 of auxiliary request 4 reads as claim 1 of the main request except that, after the second occurrence of "wherein", the claim reads as follows:

"the auto-injector (100) is activated when the end surface (152) of the needle cover (150) is pressed against an injection site,
wherein the actuation assembly (130) comprises:
an outer body (230);
an inner body (330) operatively coupled to the outer body (230);
a collet (430) operatively coupled to the inner body (330); and
an energy source (530), and
wherein:
the collet (430) has an opening formed on one end,

the auto-injector (100) further comprises a release pin (120) removably attached to the actuation assembly (130), and
the release pin (120) is removably received in the opening in the collet (430) to prevent operation of the actuation assembly (130)."

Claim 1 of auxiliary request 5 reads as claim 1 of auxiliary request 2, with the following wording added at the end of the claim:

", and
wherein:
the collet (430) has an opening formed on one end,
the auto-injector (100) further comprises a release pin (120) removably attached to the actuation assembly (130), and
the release pin (120) is removably received in the opening in the collet (430) to prevent operation of the actuation assembly (130)".

Claim 1 of auxiliary request 6 reads as claim 1 of the main request except that, after the second occurrence of "wherein", the claim reads as follows:

"the auto-injector (100) is activated when the end surface (152) of the needle cover (150) is pressed against an injection site,
wherein the first locking assembly further includes a tab (342) constructed and arranged to contact the cartridge (160), and
wherein the tab (342) causes the first locking assembly to pivot in response to movement of the cartridge (160) during a medicament dispensing operation such that the locking surface (347a)

pivots out of contact with the surface on the needle cover (150)."

Claim 1 of auxiliary request 7 reads as claim 1 of auxiliary request 6, with the following wording added at the end of the claim:

", and
wherein the actuation assembly (130) comprises:
an outer body (230);
an inner body (330) operatively coupled to the outer body (230);
a collet (430) operatively coupled to the inner body (330); and
an energy source (530)".

Claim 1 of auxiliary request 8 reads as claim 1 of auxiliary request 6, with the following wording added at the end of the claim:

",
wherein the actuation assembly (130) comprises:
an outer body (230);
an inner body (330) operatively coupled to the outer body (230);
a collet (430) operatively coupled to the inner body (330); and
an energy source (530).
wherein the collet (430) has at least one tapered portion (434), and the outer body (230) of the actuation assembly (130) has at least one surface (239a) constructed and arranged to contact the at least one tapered portion (434), and
wherein the at least one surface (239a) is constructed and arranged to contact the at least one tapered portion (434) to compress the collet

(430) in an area around the elongated opening (432) such that the collet (430) is released from the inner body (330) in response to application of an activation force".

Claim 1 of auxiliary request 9 reads as claim 1 of auxiliary request 6, with the following wording added at the end of the claim:

",
wherein the actuation assembly (130) is mounted within the housing (110) adjacent an open end in the housing (110), and
wherein the auto-injector further comprises a release pin (120) removably attached to the actuation assembly (130) and the auto-injector (100) is not operable when the release pin (120) is connected to the actuation assembly (130)".

Claim 1 of auxiliary request 10 reads as claim 1 of auxiliary request 6, with the following wording added at the end of the claim:

",
wherein the actuation assembly (130) comprises:
an outer body (230);
an inner body (330) operatively coupled to the outer body (230);
a collet (430) operatively coupled to the inner body (330); and
an energy source (530), and
wherein:
the collet (430) has an opening formed on one end,
the auto-injector (100) further comprises a release pin (120) removably attached to the actuation assembly (130), and

the release pin (120) is removably received in the opening in the collet (430) to prevent operation of the actuation assembly (130)".

Claim 1 of auxiliary request 11 reads as claim 1 of auxiliary request 6, with the following wording added at the end of the claim:

",
wherein the actuation assembly (130) comprises:
an outer body (230);
an inner body (330) operatively coupled to the outer body (230);
a collet (430) operatively coupled to the inner body (330); and
an energy source (530).
wherein the collet (430) has at least one tapered portion (434), and the outer body (230) of the actuation assembly (130) has at least one surface (239a) constructed and arranged to contact the at least one tapered portion (434),
wherein the at least one surface (239a) is constructed and arranged to contact the at least one tapered portion (434) to compress the collet (430) in an area around the elongated opening (432) such that the collet (430) is released from the inner body (330) in response to application of an activation force, and
wherein:
the collet (430) has an opening formed on one end,
the auto-injector (100) further comprises a release pin (120) removably attached to the actuation assembly (130), and
the release pin (120) is removably received in the opening in the collet (430) to prevent operation of the actuation assembly (130)".

Claim 1 of auxiliary request 12 reads as claim 1 of the main request except that the second occurrence of the word "therein" has been replaced with the following wording:

"in the front end of the needle cover (150)".

VI. The appellant's arguments, where relevant to the present decision, can be summarised as follows:

Admission of respondent's arguments

The respondent's letter of 15 May 2021 or the arguments submitted with that letter should not be admitted into the proceedings. The letter was full of new arguments which changed the respondent's case after notification of the summons to oral proceedings. In particular, the respondent had raised a new argument according to which the end surface of the needle cover had to be interpreted as a wall. There were neither exceptional circumstances nor cogent reasons for presenting the appellant and the Board with this argument so late.

Extension of subject-matter

Claim 1 of the patent as granted defined two openings in the needle cover: a rear opening and an opening in the front end surface through which the needle could pass during a medicament dispensing operation. Since the needle had to pass through an opening at the front end surface, which was a two-dimensional entity, another opening was inherently defined at an opposite upper surface of the needle cover, for permitting the needle to access the opening at the front end surface. Such a configuration was clearly disclosed in the

application as filed, for example in Figures 5 and 7.

Whether or not paragraph [0046] of the patent might designate a thin three-dimensional element as the end surface of the needle cover was irrelevant. The description should not be used to give another meaning to a clear claim feature. Moreover, this paragraph only mentioned that a spring was compressed between the end surface and the cartridge container. This did not mean that the spring had to contact the end surface.

Moreover, an infinite number of openings was defined by the interior of the needle cover, as shown in the figures of the application as filed. The needle could certainly pass through many of these openings during a medicament dispensing operation.

Finally, the term "rear" provided no technical contribution for distinguishing the claimed subject-matter from the prior art. It followed that, according to decision G 1/93, this term could not add subject-matter. Therefore, claim 1 of the patent as granted did not comprise added subject-matter. The same conclusions applied to each of auxiliary requests 1 to 11.

Auxiliary request 12

Auxiliary request 12 had been filed in response to the respondent's new argument that the end surface disclosed in the application as filed should be construed as meaning a wall. The possibility of responding to this new argument was an exceptional circumstance justifying the admission of a new auxiliary request.

VII. The respondent's arguments, where relevant to the present decision, can be summarised as follows:

Admission of respondent's arguments

The arguments submitted by letter dated 15 May 2021 did not change the respondent's case. In particular, the objection of added subject-matter directed to the term "rear opening" had been present since the beginning of the appeal proceedings and the Opposition Division had even based its decision on it. The arguments provided with the letter dated 15 May 2021 addressed certain points which seemed to be more important than others in this respect, in view of the Board's preliminary opinion which accompanied the summons to oral proceedings. They refined but did not change the respondent's case. Such a refinement based on the elaboration of some arguments was in line with the findings in decision T 247/20, according to which the oral proceedings would serve no purpose if they were limited to mere repetitions of earlier submissions.

Extension of subject-matter

Claim 1 of the patent as granted defined two openings in the needle cover for permitting passage of the needle and the needle assembly during a medicament dispensing operation; however, the application as filed disclosed only one opening in the needle cover (through its end surface), which permitted passage of the needle during a medicament dispensing operation. The only rear opening disclosed in the application as filed was at the rear end of the needle cover. This opening was visible in Figure 9, where ledge 243 of the cartridge container, as described in paragraph [0013], engaged the needle cover. This further opening, however, did

not permit passage of the needle assembly during a medicament dispensing operation. Interpreting the opening through the end surface of the needle as two openings was artificial and went against the original disclosure, which identified the end surface as the full thickness from the front side to the rear side of the needle cover (paragraph [0102]). The application as filed disclosed only one opening through the end surface, covering the full distance from the rear side to the front side. The internal lumen of the needle cover could not be considered to be an opening either. There was therefore no direct and unambiguous disclosure of a rear opening of the needle cover as claimed in the application as filed. Such a rear opening limited the claimed subject-matter, as it required two openings, and not just one as originally disclosed. Hence, the appellant's reference to decision G 1/93 was irrelevant. Therefore, claim 1 of the patent as granted comprised added subject-matter. The same conclusions applied to each of auxiliary requests 1 to 11.

Auxiliary request 12

Auxiliary request 12 had been filed after notification of the summons to oral proceedings. There were no exceptional circumstances for filing this request at such a late stage. The respondent's case had never changed and the appellant could have responded to it before. Therefore, auxiliary request 12 should not be admitted into the proceedings.

Reasons for the Decision

1. The invention relates to an auto-injector for injecting a medicament into a user.

Auto-injectors typically allow a user to self-administer a predetermined dose of a medicament composition subcutaneously or intramuscularly. They may be used in an emergency situation, for example to treat anaphylactic reactions and to administer antidotes for certain poisons, such as chemical nerve agents (paragraph [0004] of the patent).

The patent as granted discloses an auto-injector depicted in three different operating positions in Figures 2, 7 and 9, reproduced below.

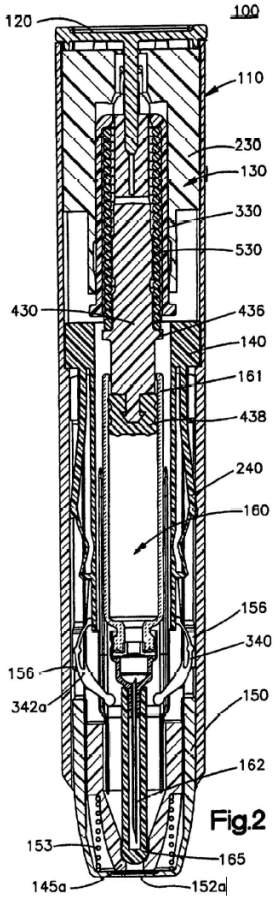

Fig.2

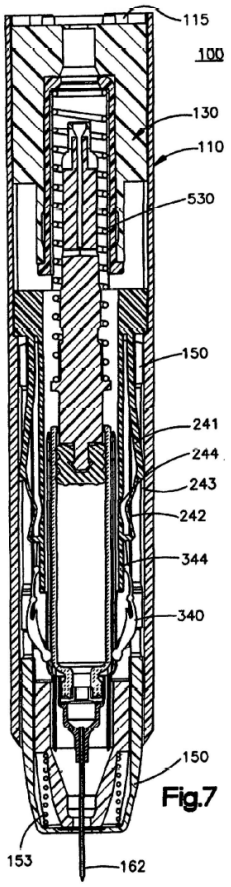

Fig.7

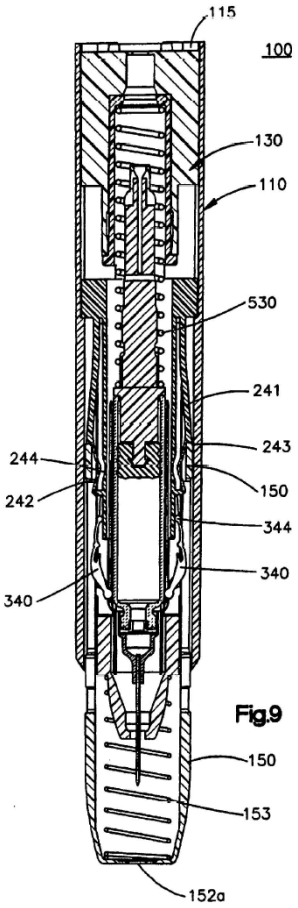

Fig.9

The auto-injector includes a housing (110), a cartridge container (140) disposed within the housing, a cartridge (160) containing a medicament and including a needle assembly with a needle (162), an actuation assembly (130) providing a stored energy source capable of driving the needle to permit injection of the medicament into a user, and a needle cover (150) having a first retracted locked position (Figures 2 and 7) and a second extended locked position (Figure 9).

According to claim 1 of the patent as granted, the needle cover has a rear opening for permitting the passage of the needle assembly there through during a medicament dispensing operation, and an end surface having an opening sized to permit passage of the needle there through. The auto-injector is activated when the end surface of the needle cover is pressed against an injection site.

The needle cover and its locked positions are intended to ensure the safety of use of the auto-injector as claimed.

2. Admission of respondent's arguments

Insofar as they are relevant for the present decision, the respondent's arguments filed by letter dated 15 May 2021, in particular the argument according to which the end surface of the needle cover had to be interpreted as a wall, concern the question of whether the application as filed disclosed a rear opening together with an opening in the end surface of the needle cover as defined in claim 1 of the patent as granted. The appellant argued that these arguments should not be admitted into the proceedings.

Article 13 RPBA concerns the admissibility of amendments to a party's appeal case after it has filed its grounds of appeal or reply. It is at the Board's discretion whether or not to admit these amendments.

The respondent argued that the arguments filed by letter dated 15 May 2021 did not change its case.

The Board shares the respondent's view.

In the impugned decision, the Opposition Division considered that the definition of the rear opening in claim 1 of the patent as granted had no basis in the application as filed (points 14.1 to 14.5).

In its reply to the statement of grounds dated 27 December 2018, the respondent submitted arguments as to why, in its view, the definition of both a rear opening and an end opening in the needle cover which permitted passage of the needle assembly or needle during a medicament dispensing operation added subject-matter (page 1, last paragraph to page 2, first paragraph, and page 5, third paragraph, to page 6, second paragraph, of the reply). Moreover, it expressly referred to paragraph [0102] of the application as filed (page 7, first paragraph).

The arguments filed by letter dated 15 May 2021 corroborate the respondent's objection, providing a view as to why the opening in the end surface could not be broken into two openings. The arguments refer to the wording of claim 1 of the patent as granted and to paragraph [0102] of the application as filed. They further illustrate and refine the objection, aimed at addressing the Board's preliminary opinion accompanying the summons to oral proceedings while remaining within

the framework of the objection presented with the reply to the statement of grounds. Such further illustration and refinement of the objection is within the boundaries of the discussion which can reasonably be expected even during the oral proceedings. In this respect the Board agrees with the conclusions drawn in decision T 247/20 (point 1.3 of the Reasons) that such further illustration and refinement does not amount to a change of case and that oral proceedings would serve no purpose if the parties were limited to presenting a mere repetition of the arguments put forward in writing.

Since the arguments filed by letter dated 15 May 2021 concerning the question of whether the application as filed disclosed a rear opening together with an opening in the end surface of the needle cover do not amount to a change of the respondent's case, the Board has no discretion not to admit them into the proceedings under Article 13 RPBA.

Hence, these arguments are part of the appeal proceedings.

3. Extension of subject-matter

3.1 Claim 1 of the patent as granted defines, and hence discloses, two distinct openings in the needle cover: a rear opening formed in the needle cover to permit the passage of the needle assembly there through during a medicament dispensing operation and an opening in an end surface, the latter opening being sized to permit passage of the needle there through.

It has to be assessed whether the application as filed

directly and unambiguously disclosed two such openings.

3.2 Claim 1 of the application as filed defines a needle cover "having an opening formed therein sized to permit the passage of the needle assembly there through during a medicament dispensing operation".

Paragraph [0102] of the application as filed reads:

> *"[...] The needle cover 150 has a generally elongated hollow body 151 [...] One end of the hollow body 151 is tapered having an enclosed end surface 152. The end surface 152 has an opening 152a sized to permit the passage of the needle of the cartridge 160 therethrough during an injection operation, as shown in Figures 7 and 8. The end surface 152 is intended to be placed on the injection surface of the user during operation of the auto-injector 100 A needle cover spring 153 is compressed between the end surface 152 of the needle cover 150 and the cartridge container 140, as shown in Figures 1, 2, 4, 5, 7, and 9."*

Figures 39 and 43 comprise reference signs indicating the end surface and the opening as shown in the reproduction of parts of these figures below.

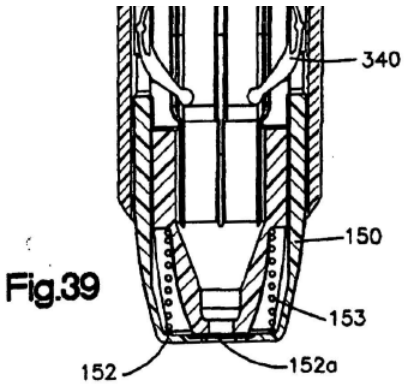

Fig.39

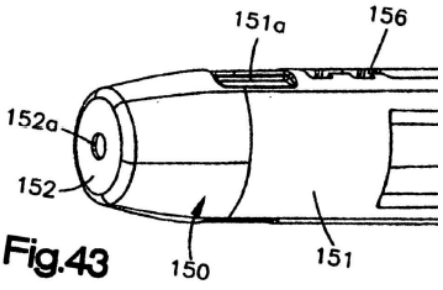

Fig.43

The application as filed therefore discloses a needle cover with an end surface provided with an opening which permits the passage of a needle through the surface and, more generally, through the needle cover, during a medicament dispensing operation.

The application as filed does not directly and unambiguously disclose any further (rear) opening which may permit the passage of the needle through the needle cover during a medicament dispensing operation. It is common ground that the rear opening at the end of needle cover 150, opposite end surface 152, does not permit the passage of the needle through the needle cover during a medicament dispensing operation.

3.3 It should be noted that, as the respondent pointed out, the application as filed designates end surface 152 as the full thickness from the front side to the rear side of the needle cover. This can be derived from the figures and from the explicit disclosure in paragraph [0102] that the needle cover spring "is compressed between the end surface 152 of the needle cover 150 and the cartridge container 140". This is not a matter of giving another meaning to a clear claim feature, as the appellant put it, but of assessing the disclosure of the application as filed.

The appellant's argument that this sentence did not mean that the spring had to contact the end surface is not convincing; in view of the figures, too, the application as filed would not have specifically mentioned the end surface but rather the needle cover if it had not implied that an end of the spring was in contact with the end surface.

The appellant argued that the end surface defined in claim 1 of the patent as granted had to be considered to be a two-dimensional entity and that, therefore, another rear opening was inherently defined at an opposite upper surface of the thin wall of the needle cover delimited by the end surface on the lower side; however, such an interpretation goes against the common use of the language as it would be understood by the person skilled in the art and could only be accepted if there were clear and unambiguous hints in the patent that exactly this was meant. As explained above, the patent does not provide such hints. On the contrary, it designates end surface 152 as the full thickness from the front side to the rear side of the needle cover.

The appellant's argument that an infinite number of openings was defined by the interior of the needle cover is not convincing. For the person skilled in the art, the internal lumen of a somehow tubular element is not an opening in this element. An opening has to provide access to the interior of the element.

A claim defining two distinct openings as explained above is more limited in scope than a claim defining a single opening. It follows that the definition of the second (rear) opening in claim 1 of the patent as granted provides a technical contribution for distinguishing the claimed subject-matter from the prior art. Hence, the appellant's reference to decision G 1/93 is irrelevant.

3.4 In conclusion, the subject-matter of claim 1 of the patent as granted extends beyond the content of the application as filed. Hence, the ground for opposition under Article 100(c) EPC prejudices the maintenance of

the patent on the basis of the main request.

3.5 It is common ground that claim 1 of each of auxiliary requests 1 to 11 contains the same problematic definition of the rear opening formed in the needle cover. Hence, on the grounds of added subject-matter (Article 123(2) EPC), none of these requests can be allowed either.

4. Auxiliary request 12

Auxiliary request 12 was filed during the oral proceedings and constituted an amendment to the appellant's case, aimed at overcoming the objection of added subject-matter.

Under Article 13(2) RPBA any amendment to a party's appeal case made after notification of a summons to oral proceedings shall, in principle, not be taken into account unless there are exceptional circumstances, which have been justified with cogent reasons by the party concerned.

The appellant argued that auxiliary request 12 had been filed in response to the respondent's new arguments filed by letter dated 15 May 2021.

However, the Board has already established that these arguments, which do not amount to a change of the respondent's case, are within the boundaries of the discussion which can reasonably be expected even during the oral proceedings.

Hence, there are no exceptional circumstances, justified with cogent reasons, which may support the admissibility of a new auxiliary request during the

oral proceedings.

Therefore, auxiliary request 12 is not admitted into the appeal proceedings under Article 13(2) RPBA.

5. It follows that the patent cannot be maintained on the basis of any of the appellant's requests.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

D. Hampe M. Alvazzi Delfrate

Decision electronically authenticated