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Datasheet for the decision of 6 October 2022

Case Number: T 0705/18 - 3.2.01

Application Number: 10179733.0

Publication Number: 2319560

IPC: A61M5/20, A61M5/32

Language of the proceedings: EN

Title of invention:
Injection device

Patent Proprietor:
Cilag GmbH International

Opponents:
EIP Limited
Sanofi-Aventis Deutschland GmbH

Headword:

Relevant legal provisions:
EPC Art. 100(c), 123(2), 56
RPBA Art. 12(2), 12(4)

Keyword:
Amendments - allowable (no) - extension beyond the content of the application as filed (yes)
Late-filed evidence - submitted with the statement of grounds of appeal - admitted (no) - request could have been filed in first instance proceedings (yes)
Late-filed request - submitted with the statement of grounds of appeal - admitted (yes) - request could have been filed in first instance proceedings (no)
Inventive step - auxiliary request 3 (yes) - could-would approach

Decisions cited:
T 0101/87, T 0724/08

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 0705/18 - 3.2.01

D E C I S I O N
of Technical Board of Appeal 3.2.01
of 6 October 2022

Appellant: (Opponent 1)	EIP Limited Fairfax House 15 Fulwood Place London WC1V 6HU (GB)
Representative:	EIP Fairfax House 15 Fulwood Place London WC1V 6HU (GB)
Respondent: (Patent Proprietor)	Cilag GmbH International Gubelstrasse 34 6300 Zug (CH)
Representative:	Carpmaels & Ransford LLP One Southampton Row London WC1B 5HA (GB)
Party as of right: (Opponent 2)	Sanofi-Aventis Deutschland GmbH Industriepark Höchst Bldg. K801 65926 Frankfurt am Main (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 19 January 2018 rejecting the opposition filed against European patent No. 2319560 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman	P. Guntz
Members:	A. Wagner
	J. J. de Acha González
	P. Guntz

Summary of Facts and Submissions

I. The appeal of the opponent 1 ("opponent") lies against the decision of the opposition division to reject the opposition filed against European patent No. 2319560 pursuant to Article 101(2) EPC.

II. In its decision, the opposition division held, among others, that the subject-matter of claim 1 of the patent as granted did not extend beyond the content of the application as originally filed (Article 100(c) EPC).
With regard to Article 100(a) EPC in combination with Article 56 EPC, the opposition division found, inter alia, that the subject-matter of claim 1 was inventive over the following prior art:

D2: WO 99/10030

combined with one of the documents

D3: US 2,147,616,
D19: US 3,076,455,
D20: US 5,356,395, or
D21: AU 7 515 387.

III. Together with the statement of grounds of appeal the appellant (opponent) filed the following document:

D27: US 2003/0105430 A1

IV. Oral proceedings were held before the board on 6 October 2022.

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

The respondent (patent proprietor) requested that the appeal be dismissed (main request), or, in the alternative, that the patent be maintained in amended form according to any of the auxiliary requests 1 to 10 filed with the reply to the statement of grounds of appeal, whereby auxiliary request 3 comprises an amended description submitted during the oral proceedings before the board.

The party as of right (opponent 2) has not taken any procedural action during the appeal proceedings and accordingly has not submitted any requests.

VI. Claim 1 of the **main request** (patent as granted) reads as follows (feature numbering according to the impugned decision):

1. An injection device (110) comprising:

1.1 a housing (112) adapted to receive

1.2 a syringe (114) having a relatively wide reservoir portion and a relatively narrow discharge nozzle, so that

1.3 the syringe (114) is movable between a retracted position in which the discharge nozzle is contained within the housing (112) and an extended position in which the discharge nozzle extends from the housing (112) through an exit aperture (128); and

1.4 a drive (134) that acts upon the syringe (114) to advance it from its retracted position to its extended position and discharge its contents through the discharge nozzle, characterised by

1.5 a syringe carrier (150) for carrying the syringe (114) as it is advanced and restraining its advancement beyond its extended position,

1.6 wherein the syringe carrier (150) is adapted to support the syringe (114) between the reservoir portion and the discharge nozzle,

1.7 wherein the syringe carrier (150) comprises a sheath (154) which is split along its length so that the syringe (114) can be clipped into the syringe carrier (150).

Claim 1 of **auxiliary request 1** differs form granted claim 1 in that it further includes the following feature:

1.8 wherein the sheath has a first internal diameter along its length, and a first end with a second internal diameter which is smaller than the first internal diameter so that the first end of the sheath is adapted to support the syringe between the reservoir portion and the discharge nozzle.

Auxiliary request 2 is based on the main request, wherein the following feature is added to claim 1:

1.9 wherein the sheath surrounds the reservoir portion of the syringe.

Auxiliary request 3 is based on the main request, wherein both features 1.8 and 1.9 are added to claim 1.

VII. The appellant's (opponent's) arguments relevant to the present decision may be summarized as follows:

Main request - Article 100(c) EPC

Feature 1.7, taken from the description, originally only was disclosed in combination with the following additional features A and B:
(A) The sheath was 'for surrounding the reservoir portion of the syringe';
(B) the sheath had 'a first internal diameter along its length, and further having a first end with a second internal diameter which is smaller than the first internal diameter so that the first end of the sheath is adapted to support the syringe between the reservoir portion and the discharge nozzle'.

The opposition division did not refer to the right passages in the original description, i.e. page 2, lines 24 to 28, where the sheath was defined for the first time including features A and B. Also original claims 5 and 6 defined the split sheath only together with features A and B.

Admissibility of new line of argumentation

In the letter dated 1 September 2022, the patent proprietor argued for the first time that features A and B were implicit in claim 1. This line of argumentation was late filed and was not to be admitted into appeal proceedings under Article 13(1) RPBA 2020. Before it was always argued that feature 1.7 was

separate from features A and B.

Additionally, features A and B were not implicit in claim 1. A sheath that only surrounded the nozzle would fall under the claim wording but was originally not disclosed and did not correspond to a sheath surrounding the reservoir. Additionally, single internal protrusions of the sheath may retain the syringe without a second internal diameter. Such an embodiment would fall under the claim but was likewise originally not disclosed.

Auxiliary requests 1 to 3 - admissibility

Auxiliary requests 1 to 3 were filed for the first time in appeal. All three auxiliary requests were directed to objections under Article 123(2) EPC raised in detail in opposition proceedings. These requests should thus have been presented in the first instance as a fall back position for the patent proprietor during oral proceedings before the opposition division. Auxiliary requests 1 to 3 should not be admitted into appeal proceedings under Article 12(4) RPBA 2007.

Admissibility of D27

D27 should be admitted as it was *prima facie* highly relevant under Article 54 EPC and Article 56 EPC. Three embodiments of D27 took away novelty of the claimed injection device.

Auxiliary request 3 - Article 56 EPC

D27 or alternatively D2 may serve as closest prior art. In the appellant's opinion, claim 1 lacked an inventive step over D27 taken alone or read in combination with

common general knowledge or over D2 combined with D27.

The opposition division erred that claim 1 was inventive over D2 in combination with any of the documents D3, D19, D20 or D21. Concerning these findings, it was referred to the submissions in opposition.

VIII. The respondent's (patent proprietor's) arguments relevant to the present decision may be summarised as follows:

Main request - Article 100(c) EPC

Claim 1 as granted was based on claim 1 as originally filed wherein feature 1.7 was added. Feature 1.7 could be found literally on page 5, lines 23, 24, of the description as originally filed.
As found by the opposition division, the sheath originally was disclosed as solving two independent problems. One was the problem of sterile insertion of the syringe being solved by the sheath being split, see also page 3, lines 14 to 20 (feature 1.7). The other problem was directed to a breakage of the syringe solved by the sheath surrounding the reservoir portion of the syringe, see page 5, lines 27 to 30. The split obviously was contradictory to said other problem aiming to contain the broken glass in case of breakage. The split provided a gap allowing broken glass to escape. The features were thus not inextricably linked and the omission of features A and B did not result in extended subject-matter.

Admissibility of new line of argumentation

In the preliminary opinion of the board, point 1.4, it was stated for the first time in the proceedings that the feature "*sheath is split along its length*" implied a longitudinal extension. In direct reply hereto it was argued that, because of the implicit longitudinal extension, the sheath was then also implicitly suitable "for surrounding the reservoir portion of the syringe". Furthermore, feature 1.5 implied feature B because it defined that the syringe carrier restrained the advancement of the syringe beyond its extended position.

Auxiliary requests 1 to 3 - admissibility

Under the old rules of procedure of the boards of appeal, it was still possible to wait for a reaction of the opposition division before reacting to the objections raised. At no point in the opposition proceedings, the patent proprietor was confronted with a negative opinion in view of Article 100(c) EPC. Thus, there was no reason to file auxiliary requests 1 to 3 in the first instance.
All three auxiliary requests were directed to the objections under Article 100(c) EPC maintained by the opponent in appeal. The requests were filed in direct reply to the opponent's statement of grounds of appeal. Additionally, the amendments made in auxiliary requests 1 to 3 were not presented for the time in appeal but were already included in auxiliary requests 5 and 6 of the opposition proceedings.

Admissibility of D27

D27, filed with the opponent's statement of grounds of

appeal, should not be admitted into appeal proceedings. The opposition was rejected and accordingly there was no need to react on any amendment made to the claims. D27 did not address any particular point arisen in the opposition proceedings. D27 could not be considered as a legitimate reaction to the first instance decision. With the filing of D27 and the respective objections, the opponent opened a completely fresh case and tried to prolong the opposition period. According to T 0101/87, the appeal should not be used as an attempt for further search to find better documents than in the first instance proceedings.

Auxiliary request 3 - Article 56 EPC

D2 might be seen as the closest prior art. The opposition division was right in concluding that the skilled person had no motivation to modify the syringe carrier of D2 (sleeve 25) according to feature 1.7. The reasoning of the opposition division given under point 23 of the impugned decision with regard to the main request applied mutatis mutandis to the subject-matter of claim 1 of auxiliary request 3.

Reasons for the Decision

1. **Main request - Article 100(c) EPC**

1.1 The subject-matter of claim 1 as granted extends beyond the content of the application as filed (Article 100(c) EPC). The introduction of feature 1.7 - the syringe carrier comprises a sheath which is split along its length - results in an unallowable intermediate generalisation.

1.2 The board follows the argument of the appellant (opponent) that the sheath as defined in feature 1.7 only was disclosed in combination with
- feature A "*for surrounding the reservoir portion of the syringe*" and
- feature B "*the sheath has a first internal diameter along its length, and further having a first end with a second internal diameter which is smaller than the first internal diameter so that the first end of the sheath is adapted to support the syringe between the reservoir portion and the discharge nozzle*".

1.3 Even if feature 1.7 can be found literally on page 5, lines 23 and 24, of the description as originally filed, the features 1.7, A and B are consistently disclosed in combination throughout the description, claims and drawings of the application as filed.

1.4 The relevant passages in the application as filed as cited by the appellant (opponent) are:
- the general part of the description (page 2, lines 24 to 28: "*The syringe carrier may further comprise a sheath for surrounding the reservoir portion of the syringe, having a first internal diameter along its length, and further having a first end with a second internal diameter which is smaller than the first internal diameter so that the first end of the sheath is adapted to support the syringe between the reservoir portion and the discharge nozzle. The sheath may be split.*");
- the detailed description of the embodiment (page 5, lines 9 to 30 together with figures 3, 4);
- claim 5, defining features A and B, and claim 6, being dependent on claim 5, defining feature 1.7.

1.5 The split along the length of the sheath is always presented in addition to features A and B throughout the original application. The split may have an additional advantage (sterile manufacturing process), however, this advantage is not presented independently from the solution to the problem posed. The underlying technical problem is directed to the event of syringe failure (page 1, lines 12 to 30, of the description as originally filed) and is solved by features A and B. Actually, features A and B of the sheath are disclosed as being part of the invention to solve the problem posed. When using a sheath, the solution includes features A and B.

1.6 Features A and B are not only inextricably linked to feature 1.7 but also to each other as they both refer to the event of syringe breaking (page 5 of the description as originally filed, lines 12 to 30). Both features A and B aim to reduce the likelihood of broken pieces of the syringe from escaping from the injection device. Consequently, both features A and B have to be added to claim 1 to meet the requirements of Article 100(c) EPC (see also Article 123(2) EPC).

1.7 The argument of the respondent (patent proprietor) that at least feature 1.7 solved a stand-alone problem which lay contrary to the problem solved by features A and B is not convincing.

The problem solved by the split is a secondary problem. Thus the split - if provided - still has to guarantee the primary function of the sheath, i.e. preventing broken glass from escaping from the injection device (page 5 of the description as originally filed, lines 23 to 30). This limits the size of the split, resulting in a structural relationship to features A and B.

1.8 Likewise not convincing is the argument of the respondent (patent proprietor) that features A and B were implicit in claim 1. The question of admissibility under Article 13(1) RPBA 2020 of this argument raised by the appellant (opponent) can thus remain unanswered.

1.8.1 Claim 1 defines that the sheath is split along its length so that the syringe can be clipped in. This implies that the sheath has a longitudinal extension. However, this does not imply that the sheath essentially surrounds the reservoir of the syringe. It also might surround essentially the discharge nozzle - defined as part of the syringe (feature 1.2) - without contradicting the other features of the claim.

1.8.2 The same applies for feature B. As presented by the appellant (opponent), the syringe carrier does not necessarily needs two different internal diameters to support the syringe between the reservoir and the discharge nozzle. A single internal protrusion at a uniform internal diameter would be sufficient to provide this function.

2. **Auxiliary requests 1 and 2 - Article 123(2) EPC**

As auxiliary request 1 only includes feature B and auxiliary request 2 only includes feature A, these two auxiliary requests likewise do not meet the requirements of Article 123(2) EPC. The same reasoning as for the main request applies. The question of whether these requests should be admitted into the appeal proceedings can therefore be left aside.

3. **Auxiliary request 3 - Article 12(2),(4) RPBA 2007**

3.1 According to Article 12(2) and (4) RPBA 2007, any written reply to a statement of grounds of appeal is in the appeal proceedings. The board, for the following reasons, did not exercise its discretion under Article 12(4) RPBA 2007 not to admit auxiliary request 3.

3.2 The appellant (opponent) is of the opinion, that auxiliary request 3 could and should have been filed in the first instance as the objection under Article 100(c) EPC was on the table from the beginning of the opposition proceedings.

3.3 Auxiliary request 3 combines granted claims 1 and 3. This amendment adds features A and B to granted claim 1 and is suitable to overcome the objection under Article 100(c) EPC (see points 1.2 and 1.5 above).
The board agrees with the respondent (patent proprietor) that in the first instance there was no reason to file auxiliary request 3, including amendments solely directed to the objection under Article 123(2) EPC.

3.4 In the grounds for opposition, multiple objections under Article 123(2) EPC, Article 54 EPC and Article 56 EPC were raised. The patent proprietor is not expected to file auxiliary requests including amendments directed to all objections individually and in combination which would result in numerous auxiliary request.

3.5 The board notes that in the grounds for opposition of opponent 1 and opponent 2 indeed feature A and feature B were objected, however, they were objected separately. The objection directed to the combination

of features A and B was only raised 1 month before the oral proceedings, at the same date as the patent proprietor filed the auxiliary requests. This objection, referring to both features A and B, was the only objection under Article 100(c) EPC which was upheld in appeal and substantiated in detail with the statement of grounds of appeal.

3.6 During opposition proceedings, the patent proprietor filed auxiliary requests including, besides others, amendments directed to the objection under Article 100(c) EPC, e.g. auxiliary request 3 of the first instance, corresponding to auxiliary request 6 in appeal. Thus the patent proprietor was aware of the objection and created a fall back position although the preliminary opinion of the opposition division was positive on this issue.
Auxiliary request 3 on file merely incorporates the amendments already introduced at first instance to the objections maintained in the appeal.

3.7 Therefore, auxiliary request 3 filed with the patent proprietor's reply to the opponent's statement of grounds of appeal is an adequate reaction according to the course of the proceedings.

4. **Admissibility of D27 - Article 12(4) RPBA 2007**

4.1 The board exercised its discretion under Article 12(4) RPBA 2007 to not admit D27 into the appeal proceedings.

4.2 Article 12(4) RPBA 2007 allows not to admit evidence which could (and should) have been presented in the first instance proceedings.

4.3 D27 was filed by the appellant (opponent) with the statement of grounds of appeal. According to the appellant, the document should be admitted for being *prima facie* highly relevant under Article 54 EPC and Article 56 EPC.

4.4 The board is convinced that D27, cited for a novelty objection with regard to the patent as granted, could and should have been filed during the first instance proceedings, especially within the nine month period for opposition.
The appellant (opponent) had already raised a novelty objection in its opposition and cited four documents as novelty destroying for the subject-matter of claim 1 as granted. The opposition division decided that none of these documents was prejudicial to the maintenance of the patent as granted. In accordance with T 0101/87 (reason 2) and T 0724/08, the appeal procedure does not serve to prolong the period for opposition for the opponent by attempting to find more relevant prior art than the one presented in the opposition.

4.5 As mentioned by the respondent (patent proprietor), D27 can also not be considered as being untraceable as the title as well as the document classification correspond to those commonly used in the technical field of injection devices as described in the patent in suit.

4.6 As the appellant (opponent) did not substantiate why the opposition division erred in its conclusion that claim 1 as granted was new and no arguments were submitted supporting that the filing of D27 was in reaction to any new issues arising in the opposition proceedings, D27 can not be considered as a legitimate reaction to the first instance decision. Consequently, D27 is not admitted into the appeal proceedings.

5. **Auxiliary request 3 - Article 56 EPC**

5.1 With regard to the objections of inventive step, the appellant (opponent) did not substantiate why the decision of the opposition division in view of inventive step starting from D2 in combination with one of the documents D3, D19, D20 or D21 was wrong. The first instance decision only concerns the main request (patent as granted).

5.2 In the statement of grounds of appeal as well as during oral proceedings before the board the appellant (opponent) merely referred in general terms to the opposition submissions. Such a reference is generally not taken into account in appeal proceedings (Article 12(1),(2) RPBA 2007, see also Case Law of the Boards of Appeal, 9th edition, V.A.2.6.4 a)).

5.3 The board further notes that no additional submissions were made in view of inventive step directed to the subject-matter as claimed in claim 1 of auxiliary request 3.

5.4 As the opposition division already concluded that the subject-matter of claim 1 as granted was inventive (impugned decision, point 23 ff), also the subject-matter of claim 1 of auxiliary request 3, which combines granted claims 1 and 3, was considered inventive. The Board sees no reason to deviate from these findings.

6. Description

The parties agreed that the description as submitted during oral proceedings before the board does not need further adaptation to the claims according to auxiliary

request 3. Neither has the Board any objections in this regard.

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 in amended form according to the following documents:

   - claims 1 to 7 of the auxiliary request 3 as submitted with the reply to the statement of grounds of appeal,

   - description page 2 as submitted during the oral proceedings and pages 3 to 5 of the patent specification, and

   - figures 1 to 4 of the patent specification.

The Registrar: The Chairman:

A. Voyé P. Guntz

Decision electronically authenticated