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Datasheet for the decision of 12 January 2021

Case Number: T 1348/16 - 3.2.02

Application Number: 02762777.7

Publication Number: 1437150

IPC: A61M5/28, A61M5/24

Language of the proceedings: EN

Title of invention:
2-CHAMBER TYPE PREFILLED SYRINGE

Patent Proprietor:
Takeda Pharmaceutical Company Limited

Opponent:
Vetter Pharma-Fertigung GmbH & Co. KG

Headword:

Relevant legal provisions:
RPBA Art. 12(4)
RPBA 2020 Art. 25(2)
EPC Art. 54, 56, 123(2)

Keyword:

Review of a decision of opposition decision to admit a late-filed document
Feature disclosed solely in a drawing
Novelty
Discretion not to admit a request
Amendments - added subject-matter
Inventive step

Decisions cited:

T 0169/83, T 0204/83, T 1664/06, T 1488/10, T 0226/04, T 0272/92, T 0857/91, T 1043/07

Catchword:

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Case Number: T 1348/16 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 12 January 2021

Appellant: (Patent Proprietor)	Takeda Pharmaceutical Company Limited 1-1, Doshomachi 4-chome Chuo-ku Osaka 541-0045 (JP)
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Respondent: (Opponent)	Vetter Pharma-Fertigung GmbH & Co. KG Schützenstrasse 87 88212 Ravensburg (DE)
Representative:	Kordel, Mattias Gleiss Große Schrell und Partner mbB Patentanwälte Rechtsanwälte Leitzstrasse 45 70469 Stuttgart (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 5 April 2016 revoking European patent No. 1437150 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	M. Alvazzi Delfrate
Members:	S. Dennler
	C. Schmidt

Summary of Facts and Submissions

I. The patent proprietor lodged an appeal against the decision of the Opposition Division, posted on 5 April 2016, to revoke European patent No. 1 437 150.

II. In its decision, the Opposition Division had concluded that, even amended according to any of the then first to fourth auxiliary requests filed by the proprietor, the patent and the invention to which it related did not meet the requirements of the EPC. In particular, the subject-matter of claim 1 as granted was found to be new over each of the following documents:

E2: EP 0 737 485 A1
E6: EP 0 856 324 A2
E13: US 5,851,200

but not to involve an inventive step in view of E2.

III. Oral proceedings before the Board were held by videoconference on 12 January 2021.

IV. The appellant (patent proprietor) requested that the decision under appeal be set aside and that the patent be maintained as granted as the main request or in amended form on the basis of one of the first to sixth auxiliary requests filed on 5 August 2016 with the statement setting out the grounds of appeal, with the third to sixth auxiliary requests being the first to fourth auxiliary requests underlying the impugned decision renumbered.

The appellant also requested that E13 not be admitted into the appeal proceedings.

V. The respondent (opponent) requested that the appeal be dismissed and that the revocation of the patent be confirmed.

The respondent also requested that the first and second auxiliary requests not be admitted into the proceedings.

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

"A dual-chamber type prefilled syringe comprising a cylindrical member (2) which has a base end portion (4) formed with an insertion inlet (5) for a plunger rod (7) and a front end portion (3) provided with an injection needle attaching portion (6), an end plug member (13) being inserted and fitted into a side of the base end portion (4), a middle plug member (14) being arranged between the front end portion (3) and the end plug member (13), the cylindrical member (2) having an interior area hermetically partitioned into a front chamber (15) on a side of the front end portion (3) and a rear chamber (16) on the side of the base end portion (4), the cylindrical member (2) having an inner surface between the front end portion (3) and the middle plug member (14), projected outwards to form a bypass (20) in the shape of a groove, the bypass (20) having a length in a direction of an axis (19) of the cylindrical member (2), which is made larger than the middle plug member (14),
the syringe being **characterised in that**
the bypass (20) has an inner surface an end surface of which is situated on a side of an inlet (21) formed on the side of the base end portion (4) and uprises outwards by an angle (θ) which is made larger than 45

degrees with respect to the axis (19) of the cylindrical member (2)."

For the sake of conciseness, the Board refers to the angle θ as the "uprising angle" in the following.

VII. Claim 1 of the first auxiliary request reads as follows (additions compared to claim 1 as granted highlighted by the Board):

"A dual-chamber type prefilled syringe comprising a cylindrical member (2) which has a base end portion (4) formed with an insertion inlet (5) for a plunger rod (7) and a front end portion (3) provided with an injection needle attaching portion (6), an end plug member (13) being inserted and fitted into a side of the base end portion (4), a middle plug member (14) being arranged between the front end portion (3) and the end plug member (13), the cylindrical member (2) having an interior area hermetically partitioned into a front chamber (15) on a side of the front end portion (3) and a rear chamber (16) on the side of the base end portion (4), the cylindrical member (2) having an inner surface and an outer surface between the front end portion (3) and the middle plug member (14), the inner surface and outer surface projected outwards to form a bypass (20) in the shape of a groove, the bypass (20) having a length in a direction of an axis (19) of the cylindrical member (2), which is made larger than the middle plug member (14),
the syringe being **characterised in that**
the bypass (20) has an inner surface an end surface of which is situated on a side of an inlet (21) formed on the side of the base end portion (4) and uprises outwards by an angle (θ) which is made larger than 45

degrees with respect to the axis (19) of the cylindrical member (2)."

VIII. The appellant's arguments, as far as relevant for the present decision, can be summarised as follows.

Request to exclude document E13

E13 was filed by the opponent at the beginning of the oral proceedings before the Opposition Division even though the factual framework of the case had not changed since the opponent had filed its notice of opposition. E13 was thus late-filed. It was also not *prima facie* relevant. In particular, it was not more relevant than the other documents already on file, especially E2, to which E13 refers. If it had been relevant, the Opposition Division would have based its decision with respect to inventive step on this document. But the Opposition Division did not. Therefore, the Opposition Division should have refused to admit E13 into the proceedings. E13 was therefore to be disregarded in the appeal proceedings.

Main request (patent as granted) - Novelty

A proper interpretation of claim 1 required not only that the inner surface of the cylindrical member be projected outwards to form the bypass but also the outer surface. The subject-matter of claim 1 was therefore not anticipated by the embodiments of E2, Figure 22, and E13, Figure 24, in which the bypass groove was formed as a cut-out concealed within the thickness of the cylindrical member.

Furthermore, in accordance with established case law, it was not allowable to derive any value for the

uprising angle of the inner surface from these figures, which were merely schematic representations.

For these reasons, claim 1 was new over both E2 and E13.

Admittance of the first auxiliary request

The first auxiliary request was filed to clarify what the appellant had thought, during the proceedings before the Opposition Division, to be implicit from the wording of claim 1, after it became clear, particularly from reading the impugned decision, that the Opposition Division interpreted the expression "projected outwards" differently. This request was filed at the first available opportunity to do so, as soon as the need for it had become apparent. This had been possible only once the appellant had had time to fully consider the decision and the relevance of the late-filed document E13. Hence, this request represented an appropriate and immediate reaction to the decision under appeal and was therefore to be admitted into the appeal proceedings. The fact that the proprietor declined to file further auxiliary requests in the oral proceedings before the Opposition Division was not material to the questions of filing new requests containing amended claims during the appeal proceedings.

First auxiliary request - Extension of subject-matter

The formation of the bypass groove by having both the inner and outer surfaces of the cylindrical member being projected outwards was consistently disclosed in all the embodiments described in the application as

originally filed. Claim 1 therefore contained no added subject-matter.

First auxiliary request - Inventive step

E6 was to be considered the closest prior art as it also addressed the same issue of reducing the water-pistol phenomenon. The subject-matter of claim 1 differed from the syringe disclosed in E6 by the characterising feature that the uprising angle was larger than 45 degrees. This provided a simplified solution to the same problem. The person skilled in the art would have had no motivation to modify the complex bypass shape disclosed in E6 to make the uprising angle larger than 45 degrees. Hence, the subject-matter of claim 1 involved an inventive step.

The lines of argument followed by the respondent were based on hindsight. In both E2 and E13, the bypass was formed as a cut-out, and there was no hint or suggestion that the bypass could be formed by projecting both the inner and outer surfaces of the cylindrical member.

IX. The respondent's arguments, as far as relevant for the present decision, can be summarised as follows.

Request to exclude document E13

The respondent did not comment on this issue.

Main request (patent as granted) - Novelty

Both E2, Figure 22, and E13, Figure 24, disclosed a syringe comprising all the features defined in claim 1 as granted. In particular, claim 1 merely defined that

the inner surface of the cylindrical member was projected outwards to form the bypass. This did not imply any requirement on its outer surface. Hence, this definition also encompassed bypass grooves as disclosed in these embodiments provided as cut-outs within the thickness of the wall of the cylindrical member.

Furthermore, the characterising feature of claim 1 did not define a particular value for the uprising angle but simply required that this angle was larger than 45 degrees. In both these embodiments of E2 and E13, the end surfaces of the inner surface of the bypass were shown as forming an approximate right angle with the longitudinal axis of the cylindrical member. This right angle had been deliberately used by the draughtsman, especially in contrast with the other embodiments of syringes made of glass shown in E2, for which the depicted uprising angle was much smaller. The person skilled in the art would have clearly derived from these figures of E2 and E13 that the corresponding angle was larger than 45 degrees.

Admittance of the first auxiliary request

The impugned decision followed the Opposition Division's preliminary opinion already communicated to the parties in advance of the oral proceedings. Furthermore, the bypass groove disclosed in E13 was essentially similar to the groove shown in E2. Hence, no new, surprising aspects had been added by the admittance of E13 during the oral proceedings before the Opposition Division. The appellant could have filed the first auxiliary request earlier during the proceedings before the Opposition Division, namely in response to its preliminary opinion, and at the latest during the oral proceedings before it. In fact, the

appellant had twice been given the opportunity to file further auxiliary requests at the end of the oral proceedings but declined to do so. Thus, the first auxiliary request was not to be admitted into the appeal proceedings.

First auxiliary request - Extension of subject-matter

The additional feature that the outer surface of the cylindrical member was also projected outwards to form the bypass was not originally disclosed. The only reference to an outer surface projecting outwards was found on page 14 of the description as originally filed (paragraph [0038] of the patent in suit). However, this passage concerned a very specific embodiment in which this feature was associated to other features of the bypass, in particular a specific orientation at about 60 degrees with respect to the longitudinal axis, as well as an uprising angle in the range of 50-70 degrees. It followed that the subject-matter of claim 1 was based on an unallowable intermediate generalisation of this embodiment.

First auxiliary request - Inventive step

Starting from E2 or E13, it would have been obvious to the person skilled in the art to form the outer surface of the cylindrical member so it would also project outwards to form the bypass, for example, to solve the technical problems of providing the syringe with a better grip; enhancing the stability of the cylindrical member, especially in the vicinity of the bypass; and/or reducing the quantity of material needed to manufacture the syringe. The person skilled in the art would have been prompted to do this by E2, which also disclosed bypass grooves swelling out from the

cylindrical member (such as in Figure 1), E6 and E13, which disclosed a bulging portion at an end of the cylindrical member projected outwards from it.

Starting from E6, it would also have been obvious to modify the shape of the bypass so that the uprising angle was larger than 45 degrees. For example, such a shape improved the aesthetics of the syringe. It would also have been obvious from the laws of hydrodynamics that the speed of the liquid entering the bypass would be reduced. The person skilled in the art would also have found suggestions to make the uprising angle steep in both E2 and E13, which contained embodiments in which the uprising angle was disclosed as being equal to about 90 degrees.

Hence, the subject-matter of claim 1 did not involve an inventive step starting from each of these documents.

Reasons for the Decision

1. The invention

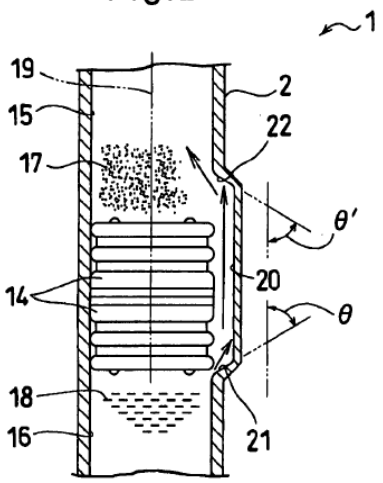
1.1 The patent in suit concerns a dual-chamber syringe comprising a cylindrical member partitioned into a front chamber and a rear chamber by a middle plug member, between a front end portion for attaching a needle and an end plug member connected to a plunger rod (Figure 1). As known in the art, a bypass provided in the cylindrical member in the form of a groove, having a length greater than the length of the middle plug member, allows both chambers to communicate with each other when the middle plug member has been pushed down to the level of the bypass by pushing the plunger rod. In this position, further pushing the plunger rod results in the liquid contained in the rear chamber

flowing into the front chamber through the bypass and dissolving or suspending a powdered medicine contained in the front chamber (paragraph [0004], Figure 12).

1.2 With the conventional design shown in Figure 12 in which the bypass is a swelling groove smoothly swelling out of the cylindrical member, a so-called "water-pistol phenomenon" may occur if the liquid enters the bypass at too high a speed, for example, when the plunger rod is pushed too quickly (paragraph [0005]-[0006]). In this situation, the liquid passing through the bypass may reach the front portion of the syringe and leak out of the needle without properly mixing with the powder in the front chamber.

1.3 To minimise this detrimental phenomenon (paragraph [0009]), the patent in suit foresees to form an end surface of an inner surface of the bypass situated on a side of an inlet to uprise outwards by an uprising angle (θ) larger than 45° with respect to the axis of the cylindrical member, as shown in Figure 2 reproduced below:

Fig.2



With such a design, the speed of the liquid flowing from the rear chamber is abruptly reduced as it enters

the bypass. This suppresses or reduces the water-pistol phenomenon (paragraphs [0014]-[0015]).

2. Request to exclude document E13

2.1 E13 was filed at the beginning of the oral proceedings before the Opposition Division, hence late. The Opposition Division admitted it into the proceedings because, after having heard the parties on this issue, it found it to be *prima facie* relevant and potentially prejudicial to the maintenance of the patent in suit (see point 16.2 of the impugned decision; points 3.4-3.9 and 3.12-3.13 of the minutes of the oral proceedings before the Opposition Division).

2.2 The decision to admit E13 was therefore based on the right principles and the Board sees no reason to doubt that the Opposition Division exercised its discretion in a reasonable way. This is not contradicted by the fact that a detailed analysis of E13 led the Opposition Division to conclude that E13 was actually not novelty-destroying and that another document, E2, represented the most relevant state of the art. The Board notes that in establishing whether a document is *prima facie* relevant, the decisive factor is not whether it is more relevant than a previously filed document but rather whether it seems to be *prima facie* relevant for the outcome of the case. Moreover, whether the late-filed document might afterwards be found, after an in-depth analysis, irrelevant or less relevant than the previously filed documents is immaterial since such an in-depth analysis is not part of the *prima facie* assessment of the relevance of a document.

2.3 Having been properly admitted by the Opposition Division, E13 thus became part of the opposition

proceedings and cannot be disregarded in the appeal proceedings (see Case Law of the Boards of Appeal of the EPO, 9th edition, 2019, V.A.3.5.4). The Board has therefore considered the respondent's objections based on this document.

3. Main request (patent as granted) - Novelty

3.1 It is common ground that E13 discloses the following features of claim 1 as granted (see Figure 24 of E13 reproduced below, referred to in the following as "Figure 24"; column 16, l. 64 - column 17, l. 12):

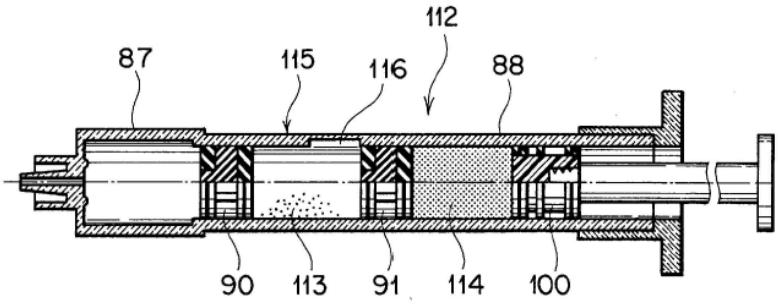
a dual-chamber type prefilled syringe (112) comprising a cylindrical member (115) which has a base end portion (top portion of cylindrical member 115 in Figure 24, located above middle plug member 91) formed with an insertion inlet for a plunger rod and a front end portion (bottom portion of cylindrical member 115 in Figure 24, located below middle plug member 91) provided with an injection needle attaching portion (formed at the very bottom end of cylindrical member 115 in Figure 24), an end plug member (100) being inserted and fitted into a side of the base end portion, a middle plug member (91) being arranged between the front end portion and the end plug member,

the cylindrical member (115) having an interior area hermetically partitioned into a front chamber (in which powdery medicine 113 may be contained) on a side of the front end portion and a rear chamber (in which liquid medicine 114 may be contained) on the side of the base end portion,

the cylindrical member being further provided with a bypass in the shape of a groove (116) (formed on the

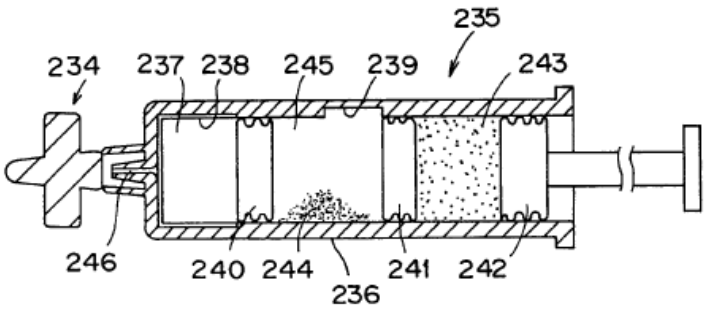
inner side of the straight portion 88 of the cylindrical member; column 17, l. 6-8) between the front end portion and the middle plug member (Figure 24), the bypass having a length in a direction of an axis of the cylindrical member, which is made larger than the middle plug member (feature implicitly resulting from the bypass function of enabling the liquid medicine to be transferred from the rear chamber to the front chamber).

F I G. 24



3.2 E13 explicitly describes (column 17, l. 8-10) that the bypass groove (116) is identical to that disclosed in E2, namely in Figure 22 reproduced below ("Figure 22" in the following; see bypass groove 239; column 16, l. 4-7). It is also common ground that the syringe (235) disclosed in this figure of E2 also comprises all the features listed above.

F I G. 2 2



3.3 According to the appellant, the feature of claim 1 according to which the inner surface of the cylindrical member was projected outwards to form the bypass was to be interpreted, as was supported by the whole description of the patent in suit, as requiring that the *cylindrical member* itself be projected outwards. By projecting the inner surface outwards, the outer surface of the cylindrical member was indeed projected outwards as well to form the bypass by means of a bulge or swollen portion of the cylindrical member. Such a bypass could therefore not be anticipated by a simple cut-out concealed within the thickness of the wall of the cylindrical member such as those disclosed in Figure 22 and Figure 24.

The Board disagrees. Claim 1 of the patent in suit is worded so clearly and unambiguously that it would have been understood without difficulty by the person skilled in the art. A plain reading of the claim confirms indeed clearly and unambiguously that it is solely the inner surface of the cylindrical member which is required to be "projected outwards" to form the bypass groove; not the cylindrical member itself. Nor does the wording of claim 1 require the bypass to have been specifically formed by projecting the wall of the cylindrical member outwards. Claim 1 therefore sets no particular requirement on the outer surface of the cylindrical member. Nor would a different conclusion be reached if the description were to be considered since the description, although presenting embodiments in which the bypass is formed by projecting the wall of the cylindrical member outwards, does not exclude arrangements which do not exhibit this feature.

In the syringes disclosed in Figure 22 and Figure 24, the bypass groove is formed on the inner side of the

cylindrical member as a cut-out within the thickness of the wall of the cylindrical member. Hence, the inner surface of the groove constitutes a part of the inner surface of the cylindrical member which is "projected outwards" (compared to the remaining part of the inner surface) to form the bypass, as required by claim 1.

3.4 In the Board's view, both Figure 22 and Figure 24 also anticipate the remaining features of claim 1, namely those of the characterising portion, which in essence define the uprising angle to be larger than 45 degrees.

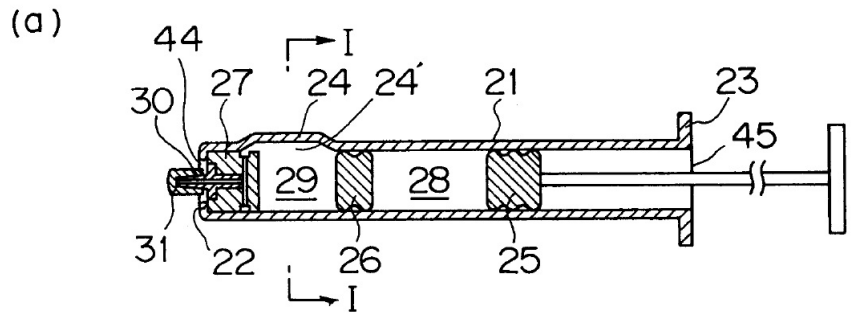
3.4.1 The appellant has argued that the text of both E2 and E13 was completely silent on the shape of the bypass grooves disclosed. In the absence of any further teaching in the description, the person skilled in the art would not have been able to derive from the figures alone, which were merely schematic representations, any technical information regarding the uprising angle.

3.4.2 The Board takes a different view. In these figures, which both illustrate a syringe with an integrally moulded cylindrical member made of a synthetic resin (E2, column 16, l. 3-4; E13, column 17, l. 3-4, 45-46), the bypass groove is clearly and consistently shown as having a rectangular cross-section (hence, with a steep uprising angle of about 90 degrees), although the remaining structure of the moulded cylindrical member noticeably differs between the two embodiments.

This rectangular cross-section is, moreover, in strong contrast with the shape of the bypass grooves consistently shown in other cross-sectional figures of E2 illustrating syringes with a cylindrical member made of glass (see e.g. Figure 1(a) reproduced below) in which the bypass groove is formed as a swelling groove

swelling smoothly out of the glass cylinder (column 6, l. 52-59), hence having a much smaller uprising angle.

F I G. 1



The person skilled in the art would therefore have recognised that the bypass shape shown in Figure 22 and Figure 24, and thus the corresponding uprising angle, had been chosen by the draughtsman of E2 and E13 purposefully. Aware of this difference, the person skilled in the art would have understood Figure 22 of E2 and Figure 24 of E13 to disclose an example of a moulding design for a bypass groove formed within a cylindrical member integrally moulded of resin, instead of being formed by swelling out the wall of a cylindrical member.

3.4.3 Contrary to the appellant's view, these figures do not show a schematic or diagrammatic view merely meant to provide an outline or general scheme of the syringes and their component parts. Rather, they are realistic technical cross-sectional representations of syringes with an integrally moulded cylindrical member having a bypass groove shaped on the inner side of this member. The person skilled in the art would thus have found in these figures a purposeful and realistic indication of a rectangular cross-sectional bypass shape and would have considered it when implementing the teaching of E2 and E13 and manufacturing the syringe by integrally moulding the cylindrical member. The fact that such a

rectangular cross-sectional bypass shape might be difficult to manufacture as argued by the appellant is immaterial to the question of novelty and could at most have a bearing in an inventive step assessment.

3.4.4 In view of the drawing quality, there is no doubt that the uprising angle shown in these figures, being close to 90 degrees, is larger than 45 degrees. In conclusion, the Board is convinced that both Figure 22 of E2 and Figure 24 of E13 constitute a disclosure of a bypass groove having an uprising angle larger than 45 degrees.

3.4.5 This interpretation of the drawings is in line with decision T 169/83 cited by the appellant itself. In that decision, the competent Board accepted that drawings could have conveyed to the person skilled in the art matters that went beyond what was disclosed in the description (see point 3.2.1 of the Reasons). In particular, the addition in claim 1 of constructional features similarly related to a specific cross-sectional shape of components of a mechanical structure, in that case a U-shape, was also considered by the Board to be allowable, even though these features were only derivable from the drawings (points 2.3 and 3.6).

3.4.6 On the other hand, the case at issue significantly differs from the other decisions cited by the appellant relevant to the disclosure of features shown solely in drawings. These decisions have therefore no bearing on the case at hand.

In T 204/83 (headnote), T 1664/06 (point 2), T 1488/10 (point 3.5), T 226/04 (point 4.3) and T 272/92 (point 3.3), certain dimensions, ratio of dimensions or

structural features of a device - not angles - were considered not to be disclosed as they had not been described but only represented in purely schematic drawings. T 857/91 (point 3.2) concerned specifically measurements taken on a photo.

In T 0143/07 (points 2.2 to 2.7), the angle in dispute was the angle of incidence of light rays entering an optical probe. However, these incident light rays had not been depicted by the draughtsman. The drawings merely schematically represented the path of a few light rays travelling within the probe. In the absence of any further teaching in the description, the competent Board refused to deduce from the drawings any particular angle of incidence for the incident light rays not drawn. Rather, the path of the light rays illustrated within the probe was considered to be merely the expression of the draughtsman's artistic freedom. This situation therefore differs significantly from the current case in which the bypass shape shown in Figure 22 and Figure 24, and thus the corresponding uprising angle, directly characterise the structure of the moulded cylindrical member and additionally appear to have been deliberately chosen by the draughtsman, as discussed in paragraph 3.4.2 above.

3.5 It follows from the foregoing that the subject-matter of claim 1 as granted lacks novelty over each of E2 and E13 (Article 54(1) and (2) EPC), contrary to the appellant's view and the Opposition Division's finding (see page 10 of the impugned decision, last paragraph).

4. Admittance of the first auxiliary request

Compared to claim 1 of the patent in suit, the subject-matter of claim 1 of the first auxiliary request has

been limited to further distinguish it from the disclosure of E2, on the basis of which the Opposition Division had motivated its decision to revoke the patent. The Board considers the filing of this request to be a legitimate reaction of the appellant to the adverse decision of the Opposition Division.

The amendment concerned, which requires that the outer surface of the cylindrical member should also be projected outwards to form the bypass, is not technically complex and merely limits the definition of the bypass without raising any new issues.

Moreover, the request was filed at the earliest possible stage of the appeal proceedings, namely with the statement setting out the grounds of appeal. Even if, as brought forward by the respondent, the appellant might have been, in theory, able to file this request at the end of the oral proceedings before the Opposition Division, the Board finds it plausible that the formulation of a suitable new request overcoming the objection was not immediately evident at that stage, especially because the preceding discussion during the oral proceedings had concentrated on the inner surface of the bypass groove.

For these reasons, the Board decided to take into account the first auxiliary request in accordance with Article 12(4) RPBA 2007, which applies in this case by virtue of the transitional provisions of Article 25(2) RPBA 2020.

5. First auxiliary request

5.1 Extension of subject-matter

The added feature that not only the inner surface but also the outer surface of the cylindrical member is projected outwards to form the bypass has been consistently disclosed for all the embodiments described in the application as originally filed from which the patent in suit is derived.

This feature is clearly visible in all the drawings, not only in the cross-sectional views (see e.g. Figure 1), where the bypass is shown as a protuberance on the cylindrical member, but also in the front views (see e.g. Figure 3), where the use of a solid line to represent the bypass suggests that it is visible from outside (contrary to other internal features such as the middle plug member 14, drawn with a dotted line).

Similarly, further support is provided by the description as filed which explicitly refers to the "outer appearance of the bypass" (p. 14, l. 20) and suggests that the protrusion of the bypass is detrimental to the "smoothness of an outer surface of the cylindrical member" (p. 14, l. 15-18). Contrary to the respondent's contention, the Board does not understand these passages to refer only to a specific bypass configuration but rather to apply generally to all embodiments disclosed. In particular, the specific angle of 60 degrees and the range of 50-70 degrees mentioned merely represent preferred values for the uprising angle to achieve an appropriate balance between manufacturing complexity and a satisfactory reduction of the water-pistol effect. Isolating the feature added in claim 1 from these angle values is thus allowable.

It follows that the subject-matter of claim 1 of the first auxiliary request does not extend beyond the

content of the application as filed (Article 123(2) EPC).

5.2 Inventive step

5.2.1 Starting from E2 or E13

Since the bypass groove in Figure 22 of E2 and Figure 24 of E13 is formed as a cut-out concealed within the thickness of the wall of the cylindrical member and given the Board's conclusion in paragraph 3.5 above, the subject-matter of claim 1 of the first auxiliary request differs from each of these known embodiments only by the added limitation that the outer surface of the cylindrical member is also projected to form the bypass.

The respondent formulated several objective technical problems allegedly solved by this distinguishing feature, namely: how to provide the syringe with a better grip; how to enhance the stability of the cylindrical member, especially in vicinity of the bypass; and/or how to reduce the quantity of material needed to manufacture the syringe. According to the respondent, it would have been obvious to the person skilled in the art faced with any of these problems to provide the cylindrical member disclosed in Figure 22 and Figure 24 with a bulge formed around the bypass, thus arriving at the subject-matter of claim 1 without exercising an inventive step. The person skilled in the art would have indeed been prompted to do so either by their common general knowledge or the suggestions in this regard in E2 and E6 (which both disclosed the distinguishing feature in the glass syringes in which the bypass swells out of the cylindrical member) or E13

(which disclosed a bulging portion 87 formed at the front end of the cylindrical member).

The Board is not convinced by the respondent's lines of argument. First, irrespective of the technical problems formulated, both E2 and E13 (which, as noted above, refer to the same bypass groove) explicitly teach to form the bypass groove on the inner side of the cylindrical member so that it does *not* protrude outwards from the straight portion of the cylindrical member (E2, column 16, l. 3-7; E13, column 17, l. 6-8). E2 even presents this feature as an advantageous way of providing the cylinder with a "smart design" (column 16, l. 7). Thus, the person skilled in the art would not realistically have included the distinguishing feature of claim 1 into the syringes of Figure 22 and Figure 24 because this would go against the teaching of E2 and E13. Rather, the person skilled in the art faced with the technical problems above would have turned to other solutions which preserve the "smart design" of the cylindrical member, for example, increasing the wall thickness to increase the stability.

Furthermore, even if the person skilled in the art would have considered the other embodiments disclosed in E2, E13 and E6, presented by the respondent as prompts towards the current invention, the person skilled in the art would have at most simply replaced the bypass groove from Figure 22 or Figure 24 *as a whole* with either a swelling groove (as disclosed in the glass embodiments of E2, see e.g. Figure 1, or in the embodiment of E6, see e.g. Figure 5) or a bulging portion formed at the intermediate portion of the cylindrical member (as disclosed in E13, column 17, l. 9-12, in place of the bypass groove). Regarding the former alternative, the Board sees no reason why in

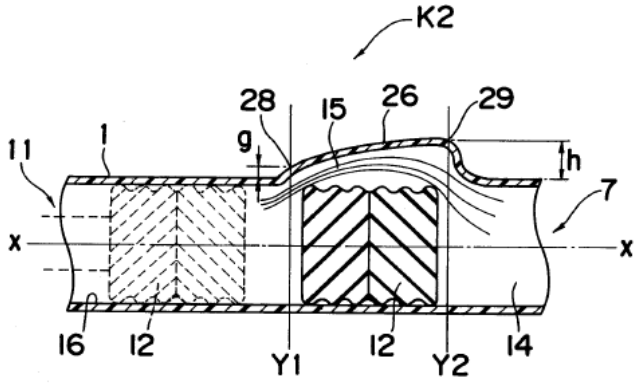
doing so the person skilled in the art would have, without the benefit of hindsight, formed the swelling groove with a rectangular cross-sectional shape - which, as discussed in paragraph 3.4.2 above, is disclosed in E2 and E13 only in connection with the moulded embodiments. Regarding the latter alternative, the resulting combination would result in a bypass formed as an annular bulging portion of the cylindrical member and not as a "groove" as required by claim 1. In both cases, the person skilled in the art would thus not have arrived at the subject-matter of claim 1.

The Board therefore comes to the conclusion that the subject-matter of claim 1 of the first auxiliary request involves an inventive step starting from E2 or E13 (Article 56 EPC).

5.2.2 Starting from E6

The Board shares the appellant's view that E6 represents a much more promising starting point for an inventive step assessment of claim 1 of the first auxiliary request since E6 not only addresses the same issue of reducing the water-pistol effect ("squirt phenomenon" in that document, see column 2, first paragraph, and column 3, l. 29-40) as in the patent in suit but also discloses (see Figure 5 reproduced below) a dual-chamber syringe with a cylindrical member having a bypass groove 26 where both the inner and outer surface of the cylindrical member are projected outwards to form the bypass.

Fig. 5



The subject-matter of claim 1 therefore differs from the syringe known from E6 by the characterising feature stipulating that the uprising angle is larger than 45 degrees. This is not in dispute between the parties.

As described in paragraph [0014]-[0015] of the patent in suit, the effect of the characterising feature is that the speed of the liquid entering the bypass groove is abruptly reduced. This allows to efficiently minimise the water-pistol phenomenon. Notably, in contrast with the complex bypass shape shown in E6 (Figure 5), this effect is achieved by the steep orientation of the end surface of the bypass *at the inlet side only*, with the uprising angle being required to be larger than 45 degrees.

The technical problem to be solved may therefore be regarded as to provide a simplified alternative way of reducing the water-pistol effect.

According to E6 (column 10, l. 8-29, and as illustrated in Figure 5), the reduction of the water-pistol effect is achieved by the specific shape of the bypass groove which is gradually bulged radially along its length. In particular, E6 teaches that the bypass height g at the inlet side (28) and the height h at the outlet side

(29) should be respectively "minimized" and "increased" (column 10, l. 20-24). Hence, the person skilled in the art would have understand from E6 that the inlet inner surface of the bypass must be shaped smoothly whereas the outlet inner surface must be steeper in comparison. Without hindsight knowledge of the current invention, the person skilled in the art, even in full knowledge of the laws of hydrodynamics, would therefore not have modified the bypass shape of E6 to include the characterising feature of claim 1 leading to a steep inlet surface because this would go against the teaching of E6.

In addition, contrary to the respondent's submission, the person skilled in the art faced with the technical problem above would not have turned to E2 or E13 since these documents do not address the water-pistol phenomenon at all. Nor does the Board find persuasive the respondent's argument that the person skilled in the art would have departed from the bypass shape taught in E6 to improve the aesthetics of the syringe.

The Board therefore comes to the conclusion that the subject-matter of claim 1 of the first auxiliary request also involves an inventive step starting from E6 (Article 56 EPC).

5.3 Description

The parties had no objection against the description. The Board is also satisfied that the description of the patent as granted is adapted to the amended claims of the first auxiliary request.

6. It follows that the patent as amended according to the first auxiliary request and the invention to which it relates meet the requirements of the EPC.

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 as amended in the following version:

- claims 1-5 according to the first auxiliary request filed on 5 August 2016 with the appellant's statement setting out the grounds of appeal

- paragraphs [0001]-[0074] of the description of the patent specification

- Figures 1-12 of the patent specification

The Registrar: The Chairman:

D. Hampe M. Alvazzi Delfrate

Decision electronically authenticated