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**Datasheet for the decision
of 24 September 2021**

Case Number: T 2188/17 - 3.2.02

Application Number: 04712153.8

Publication Number: 1598088

IPC: A61M5/28

Language of the proceedings: EN

Title of invention:

TWO CHAMBER-TYPE PRE-FILLED SYRINGE

Patent Proprietor:

Takeda Pharmaceutical Company Limited

Opponents:

NIPRO CORPORATION
Lauer, Julia

Headword:

Relevant legal provisions:

EPC Art. 56, 100(a)
RPBA Art. 12(4)
RPBA 2020 Art. 13(2)

Keyword:

Late-filed requests - First to third auxiliary requests -
admitted (yes) - Fourth to seventh auxiliary requests -
admitted (no)
Amendment after summons - exceptional circumstances (no)
Inventive step - main to third auxiliary request (no)

Decisions cited:

T 1313/04

Catchword:



Beschwerdekammern

Boards of Appeal

Chambres de recours

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Case Number: T 2188/17 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 24 September 2021

Appellant:
(Opponent 1)

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Decision under appeal:

**Decision of the Opposition Division of the
European Patent Office posted on 19 July 2017
rejecting the opposition filed against European
patent No. 1598088 pursuant to Article 101(2)
EPC**

Composition of the Board:

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

Summary of Facts and Submissions

- I. Opponent 1 has appealed against the Opposition Division's decision, posted on 19 July 2017, to reject the oppositions against European patent No. 1 598 088. The patent was opposed on the grounds of lack of novelty and lack of inventive step.
- II. The Board summoned the parties to oral proceedings and sent its preliminary opinion by a communication dated 1 March 2021.
- III. By letter dated 10 September 2021, the party as of right/opponent 2 stated that she would not be attending the oral proceedings.
- IV. Oral proceedings took place on 24 September 2021 by videoconference. In accordance with Rule 115(2) EPC and Article 15(3) RPBA 2020, they were conducted without the party as of right/opponent 2, who had not filed any arguments or requests.

The appellant requested that the decision under appeal be set aside and that the patent be revoked.

The respondent/patent proprietor requested that the appeal be dismissed (main request), or that the patent be maintained on the basis of one of the first to third auxiliary requests, filed by letter dated 31 May 2018, or one of the fourth to seventh auxiliary requests, filed by letter dated 30 July 2021.

- V. The following documents are mentioned in this decision:

D1: "Pharm Tech Japan"; Vol. 15; No. 12; pages 5, 91

to 94, 99, 100, 103, 104 and 166; December 1999
Dla: Partial English Translation of PHARM TECH

VI. Claim 1 of the main request reads as follows:

"A dual-chamber type prefilled syringe comprising:
a cylindrical body (2) which has a first end (2a)
provided with an portion (3) for attaching an
injection needle,
a front plug member (6), a middle plug member (7)
and an end plug member (8) being hermetically
fitted within the cylindrical body (2) in the
mentioned order from the first end (2a) of the
cylindrical body (2),
a first chamber (9) formed within the cylindrical
body (2) between the front plug member (6) and the
middle plug member (7) and
accommodating a first component (11),
a second chamber (10) formed within the
cylindrical body (2) between the middle plug
member (7) and the end plug member (8) and
accommodating a second component (12),
the cylindrical body (2) having an inner surface
formed with a bypass (14) in the shape of a
concave groove, the bypass (14) being longer along
an axial direction of the cylindrical body (2)
than the middle plug member (7), the first chamber
(9) being able to communicate with the second
chamber (10) via the bypass (14) when the middle
plug member (7) moves toward the side of the first
end (2a) to reach a position where the bypass (14)
is formed,
characterized in that
an inner volume (VS) of the cylindrical body (2)
between the first end (2a) of the cylindrical body
(2) and the rear end (6b) of the front plug member

(6) on the side away from the first leading end of the cylindrical body (2) is at least 60% of the volume (VC) and not more than the volume (VC) of the second component (12) at the beginning of the transfer thereof between the first chamber (9) and the second chamber (10) via the bypass."

Claim 1 of the first auxiliary request is the same as claim 1 of the main request, with the following additional wording at the end of the claim:

", wherein the front plug member is positioned within the cylindrical body till the second component has finished its transfer".

Claim 1 of the second auxiliary request is the same as claim 1 of the first auxiliary request, with the following additional wording after the term "first component (11)":

", the first component being a solid agent".

Claim 1 of the third auxiliary request is the same as claim 1 of the second auxiliary request, except that the term "60%" is replaced by "75%".

Claim 1 of each of the fourth, the fifth, the sixth and the seventh auxiliary requests is the same as claim 1 of the main, the first, the second and the third auxiliary request respectively, with the following additional wording after the second occurrence of the term "second":

", liquid,".

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

Main request - inventive step

D1, in particular Figures 1e and 1f, disclosed all the features of the preamble of claim 1 of the main request. In view of decision T 1313/04, Figures 1e and 1f even directly and unambiguously disclosed an inner volume of the cylindrical body between the first end of the cylindrical body and the rear end of the front plug member on the side away from the first leading end of the cylindrical body that was between 60% and 100% of the volume of the second component at the beginning of the transfer thereof between the first chamber and the second chamber via the bypass, as defined in the characterising portion of claim 1. A volume ratio within the claimed range was clearly derivable from a visual inspection of D1.

However, even if the figures of D1 did not directly and unambiguously disclose the volume ratio within the claimed range, the person skilled in the art starting from D1 would arrive at a volume ratio within that range in an obvious way. In particular, the questions of whether, during use of a syringe with the features of the preamble of claim 1, the claimed volume ratio would be attained, and whether liquid would be prevented from splashing out of the syringe needle (water-pistol phenomenon), could depend on various non-claimed parameters such as the size of the first chamber, the degree of compressibility of the content of the first chamber, the friction provided by the first plug member, the temperature, and the speed of movement of the rear plug member. Paragraph [0042] of the patent confirmed this dependency. Therefore, the

claimed range was broad, with uncertain boundaries. It was also arbitrary, since the problem of preventing the water-pistol phenomenon could not be solved by a volume ratio within the claimed range alone. This was indeed confirmed by the patent, according to which the water-pistol phenomenon could still occur in an example with a volume ratio within the claimed range (third example of Figure 4).

The person skilled in the art who wanted to put into practice the teaching of D1 such that the water-pistol phenomenon was at least unlikely to occur would use trial and error to adjust the various parameters involved in the transfer of the second component into the first chamber. In doing so, he or she would arrive at volume ratios within the claimed range as obvious satisfactory configurations.

Admission of the auxiliary requests

None of the auxiliary requests should be admitted into the appeal proceedings. The first to third auxiliary requests could have been filed during the first-instance proceedings and suffered from the same deficiency as the main request, and were not convergent. Moreover, the features added to claim 1 of the main request to arrive at each of these auxiliary requests lacked clarity. The Board should find these auxiliary requests inadmissible under Article 12(4) RPBA 2007.

The fourth to fifth auxiliary requests had only been filed after the summons to attend oral proceedings before the Board. They had been filed very late and were not a response to new arguments. They should not be admitted.

First to third auxiliary requests - inventive step

The subject-matter of claim 1 of each of the first to third auxiliary requests did not include any inventive features either. The feature of the front plug member being positioned within the cylindrical body till the second component had finished its transfer had been introduced without specifying the technical measures that had to be taken in order for it to be achieved. It was obvious at least in view of Figure 1g of D1, which was the same as Figure 3 of the patent. D1 also disclosed a first component in the form of a solid agent. Amending the lower limit of the range of volume ratio to 75% did not have any inventive effect and appeared to be a random selection, especially considering the uncertainty surrounding the boundaries of the range.

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

Main request - inventive step

D1 could be considered as the closest prior art and disclosed all the features of the preamble of claim 1.

D1 did not directly and unambiguously disclose an inner volume of the cylindrical body between the first end of the cylindrical body and the rear end of the front plug member on the side away from the first leading end of the cylindrical body that was between 60% and 100% of the volume of the second component at the beginning of the transfer thereof between the first chamber and the second chamber via the bypass, as defined in the characterising portion of claim 1 of the main request.

More specifically, D1 provided no clear technical teaching in that respect. Its figures were not construction drawings but diagrammatic representations having only a descriptive purpose to show how the syringe of D1 should be used. The description of D1 (according to D1a) did not even hint at the volumes as defined in claim 1 of the main request. According to established case law, dimensions obtained solely by measuring such diagrammatic representations did not correspond to the standard of clear and unambiguous disclosure.

The volumes defined in the characterising portion of claim 1 were an inevitable consequence of the syringe as claimed. Other parameters had no influence on the volumes. In particular, the temperature would only vary within small ranges in the typical conditions of use and the syringe was manufactured such that the speed of movement of the plug members did not have any relevant effect on the volumes, as confirmed by paragraph [0042] of the patent. Moreover, Figure 4 of the patent showed no difference in the volume ratio as claimed for different speeds of movement of the end plug member.

The distinguishing feature over D1 was a specific delimited range for the volume ratio which addressed the objective technical problem of minimising the water-pistol phenomenon while ensuring ease of use.

D1 did not provide any teaching for solving this problem. Hence, the person skilled in the art would have had no reason to implement the distinguishing feature in the syringe according to D1.

Admission of the auxiliary requests

The first to third auxiliary requests had been filed with the reply to the statement of grounds of appeal, in response to comments made by the appellant. They should be admitted into the appeal proceedings.

The fourth to seventh auxiliary requests had been filed in response to developments during the appeal proceedings, in particular to a new and unexpected preliminary view of the Board expressed in the communication accompanying the summons to oral proceedings. Therefore, they had been filed in exceptional circumstances and should be admitted into the appeal proceedings.

First to third auxiliary requests - inventive step

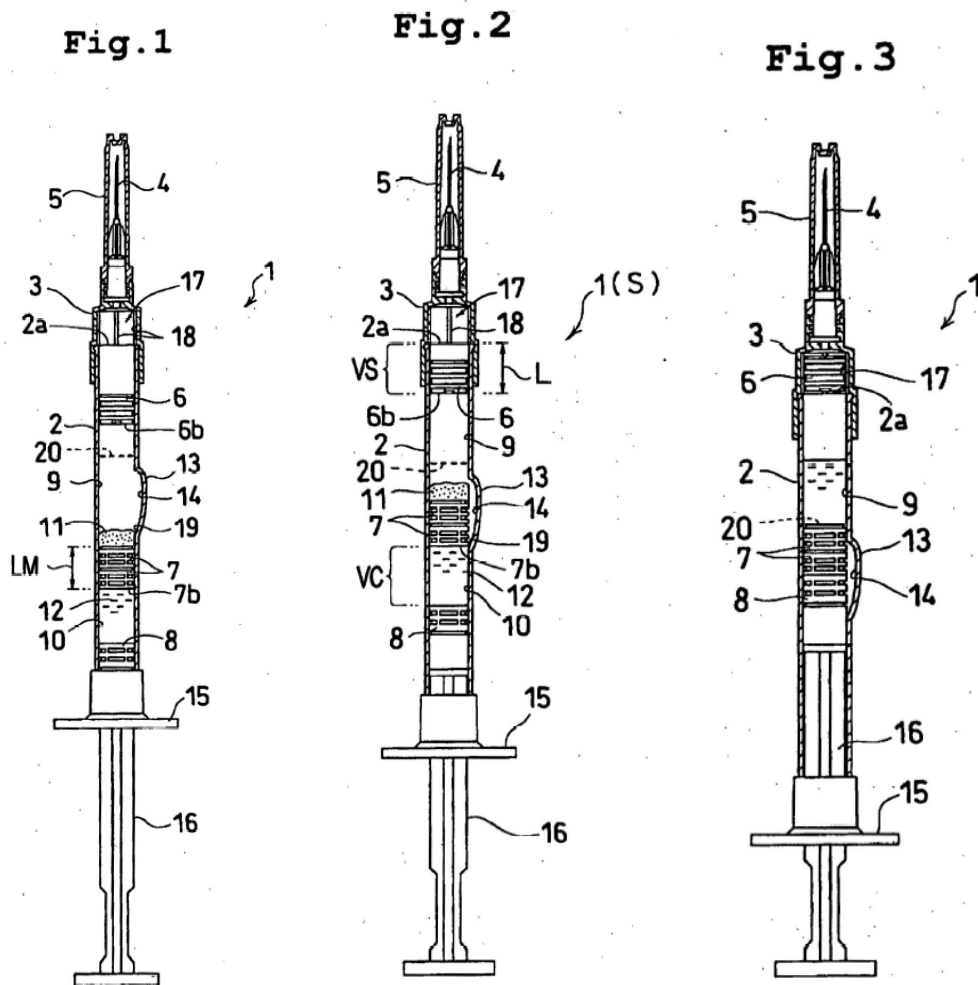
The subject-matter of claim 1 of each of the first to third auxiliary requests was inventive when starting from D1. In particular, the feature of the front plug member remaining within the cylindrical body till the second component had finished its transfer, and the feature of the lower limit of the range of the volume ratio being 75%, further distinguished the subject-matter of claim 1 of each of the auxiliary requests from D1 and ensured that the water-pistol phenomenon could not occur.

Reasons for the Decision

1. The invention relates to a dual-chamber prefilled syringe.

Such syringes are typically used to mix two components held in different chambers, immediately prior to injection.

A syringe as claimed is depicted in Figures 1 to 3 of the patent, reproduced below.



The syringe has a cylindrical body (2) with a first end (2a) for attaching an injection needle, the cylindrical body comprising a front (6), a middle (7) and an end plug member (8). A first chamber (9) accommodating a first component (11) is formed between the front and the middle plug member. A second chamber (10) accommodating a second component (12) is

formed between the middle and the end plug member.

The cylindrical body has a bypass (14) for permitting fluid communication between the first and the second chamber when the middle plug member is moved towards the first end of the cylindrical body, to a position where the bypass is formed.

Once fluid communication is possible, movement of the end plug member towards the middle plug member causes the second component to be transferred into the first chamber, where the second component is mixed with the first component to obtain an injectable composition.

The invention as claimed in the patent as granted is characterised by the inner volume (VS) of the cylindrical body between the first end of the cylindrical body and the rear end of the front plug member on the side away from the first end of the cylindrical body being at least 60% of the volume (VC) and not more than the volume of the second component at the beginning of its transfer between the first chamber and the second chamber via the bypass.

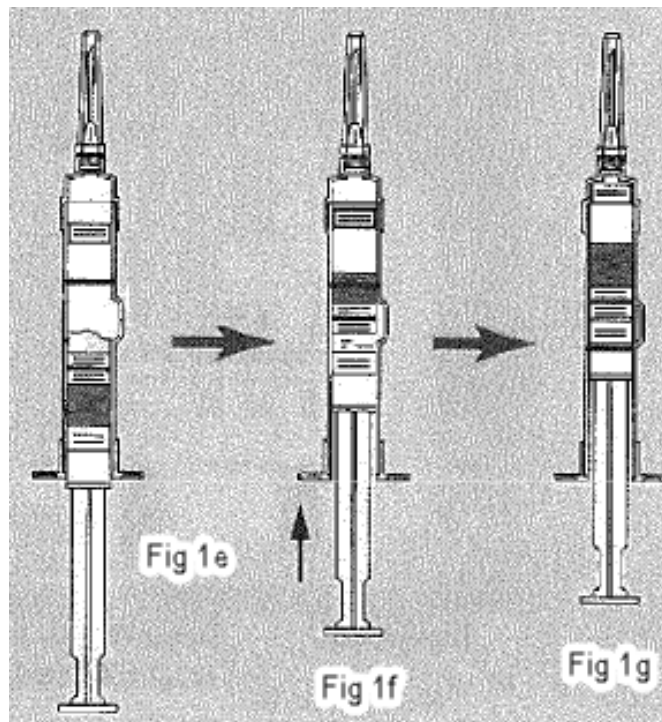
According to the patent (paragraphs [0005], [0006] and [0015] in particular), this substantially prevents the second component from splashing out of the first chamber as it is transferred and reaching the injection needle through communication means provided at the first end of the cylindrical body (water-pistol phenomenon). These communication means are to be opened when the front plunger reaches the first end of the cylindrical body.

The water-pistol phenomenon is undesirable, since it would result in incomplete mixing of the two

components.

2. Main request - inventive step

It is common ground that D1, which concerns a dual-chamber type prefilled syringe, may be regarded as the closest prior art and discloses all the features of the preamble of claim 1 of the main request (as is also apparent from D1a). The parties referred to Figures 1e to 1g of this document. They depict a sequence of use and are reproduced below.



The appellant argued that Figures 1e and 1f directly and unambiguously disclosed an inner volume of the cylindrical body between the first end of the cylindrical body and the rear end of the front plug member on the side away from the first leading end of the cylindrical body that was at least 60% of the volume and not more than the volume of the second component at the beginning of its transfer between the

first chamber and the second chamber via the bypass, as defined in the characterising portion of claim 1.

A visual inspection of Figure 1e, which represents a condition before transfer of the second component has begun, and Figure 1f, which represents a condition once transfer of the second component has begun, appears to show that the ratio of the volumes as defined falls within the claimed range. The respondent did not dispute this finding. The Board agrees with the respondent that Figures 1e and 1f of D1 cannot be considered technical construction drawings; nevertheless, the disclosure of the drawings cannot simply be ignored. In particular, in accordance with the view expressed by the deciding board in T 1313/04 (point 2.2 of the Reasons), the Board is of the opinion that the drawings of a publication form a part of its disclosure and even in the absence of any clarifying description in the written part of the publication the person skilled in the art may recognise additional features in the drawings.

In the case at hand, whether such additional features include a clear and unambiguous disclosure of a ratio of the volumes within the claimed range can be left unanswered. What the person skilled in the art is taught by the drawings in question is, at least, a syringe with a ratio of the defined volumes in the close vicinity of the claimed range.

As the respondent submitted, the feature of an inner volume of the cylindrical body between the first end of the cylindrical body and the rear end of the front plug member on the side away from the first leading end of the cylindrical body that is at least 60% of the volume and not more than the volume of the second component at

the beginning of its transfer between the first chamber and the second chamber via the bypass could be considered to address the objective technical problem of minimising the water-pistol phenomenon while ensuring ease of use.

Starting from D1, and faced with the objective technical problem, the person skilled in the art who needed to give the syringe dimensions in accordance with the teaching of D1 would notice that the higher the volume ratio the less likely the occurrence of the water-pistol phenomenon, but the more cumbersome the syringe. The potential occurrence of the water-pistol phenomenon and the total length of the syringe, which makes it easy to use or otherwise, are in direct physical dependency on the volume ratio if the amount of the second component is given (for a specific application). Starting from a volume ratio already at least in the close vicinity of the claimed range, the person skilled in the art would try out several volume ratios within that range as compromises for satisfactorily addressing the potential occurrence of the water-pistol phenomenon while preserving some ease of use.

This is all the more true because the claimed range is itself broad, and its borders are not precisely defined. The volume of the cylindrical body between the first end of the cylindrical body and the rear end of the front plug member on the side away from the first leading end of the cylindrical body at the beginning of the transfer of the second component is a parameter taken in the manner of a snapshot during the intended use of the syringe. Contrary to the respondent's view, non-claimed parameters of the syringe and of its conditions of use may have an influence on that volume.

As the appellant pointed out, for reasons of physics the size of the first chamber, the degree of compressibility of the content of the first chamber, the friction provided by the first plug member, the temperature, and the speed of movement of the rear plug member all have some influence. Indeed, paragraph [0042] of the patent, referred to by the parties, confirms the potential dependency of the volume on some of these parameters, as it states that, for manufacturing a syringe according to the invention, the potential effects caused by variations of these non-claimed parameters are to be considered when deciding the dimensions of the plug members and the surface treatment of the inner of the cylindrical body. Figure 4 of the patent, referred to by the respondent, is of little relevance in this respect, since it concerns individual experiments for which several of the non-claimed parameters are inherently fixed.

It follows that the subject-matter of claim 1 of the main request is not inventive when starting from D1. Hence, the ground for opposition of lack of inventive step under Article 100(a) EPC prejudices the maintenance of the patent according to the main request.

3. Admission of the auxiliary requests

The first to third auxiliary requests were filed by the respondent with the reply to the statement of grounds of appeal. The Board is satisfied that they were filed in response to comments made by the appellant in the statement of grounds of appeal, and it could not reasonably be expected that they should have been filed in the first-instance proceedings. Whether they fulfil all the requirements of the EPC is not a decisive

aspect for their admissibility. Under Article 12(4) RPBA 2007, which applies to the present case by virtue of Article 25(2) RPBA 2020, the Board admits these requests into the appeal proceedings.

The fourth to seventh auxiliary requests were filed only after the Board's notification of the summons to oral proceedings. Under Article 13(2) RPBA 2020 such amendments to a party's case must, in principle, not be taken into account unless there are exceptional circumstances, which have been justified with cogent reasons by the party concerned. The Board does not see any such exceptional circumstances. In particular, the provision of the Board's preliminary view, which related to an issue discussed by the parties since the beginning of the appeal proceedings, cannot be considered an exceptional circumstance. It cannot be unexpected that a preliminary view may be in favour of one or the other party. Hence, the fourth to seventh auxiliary requests are not admitted into the appeal proceedings.

4. First to third auxiliary requests - inventive step

Claim 1 of the first to third auxiliary requests respectively additionally specifies the following: the front plug member is positioned within the cylindrical body till the second component has finished its transfer; the first component is a solid agent; and the inner volume of the cylindrical body between the first end of the cylindrical body and the rear end of the front plug member on the side away from the first leading end of the cylindrical body is at least 75% of the volume of the second component at the beginning of its transfer between the first chamber and the second chamber via the bypass.

It is common ground that in D1 the first component is a solid agent.

The remaining additional features still address the objective technical problem of minimising the water-pistol phenomenon while ensuring ease of use, as also submitted by the respondent.

The Board notes that the feature that the front plug member is positioned within the cylindrical body till the second component has finished its transfer is also a parameter taken in the manner of a snapshot during the intended use of the syringe. As the appellant submitted, no specific technical measures are claimed in order for this parameter to be achieved. In other words, claimed and non-claimed parameters of the syringe and its conditions of use have an influence on whether the front plug member is positioned within the cylindrical body till the second component has finished its transfer. Moreover, paragraph [0015] of the patent states that the front plug member will be positioned within the cylindrical body till the second component has finished its transfer as a consequence of the inner volume of the cylindrical body between the first end of the cylindrical body and the rear end of the front plug member on the side away from the first leading end of the cylindrical body being at least 60% of the volume of the second component at the beginning of its transfer between the first chamber and the second chamber via the bypass. Hence, in view of this paragraph, the additional feature of the front plug member being positioned within the cylindrical body till the second component has finished its transfer would provide no limitation of the scope of the claim. Moreover, the person skilled in the art would

immediately recognise that if the front plug member is positioned within the cylindrical body till the second component has finished its transfer, the possibility that any water-pistol phenomenon takes place can be ruled out with certainty. This is because there would be no passage from the interior of the syringe to the needle.

As regards the feature restricting the claimed range of the ratio of the defined volumes, the Board notes that the range is still broad and produces no unexpected benefit that would support an inventive step with respect to the range defined in claim 1 of the main request. Indeed, whenever a compromise between two extremes has to be found, moving away from one extreme addresses the potential problems occurring at that extreme while also in some respect impairing the advantages which that extreme could bring about.

Hence, when selecting dimensions for the syringe according to D1 such that a compromise is found between satisfactorily addressing the potential occurrence of the water-pistol phenomenon and preserving some ease of use, the person skilled in the art would try out volume ratios satisfying the additional features of claim 1 of each of the first to third auxiliary requests in an obvious way if he or she was more concerned with the prevention of the water-pistol phenomenon.

It follows that the subject-matter of claim 1 of the first to third auxiliary requests is not inventive (Article 56 EPC) over D1.

5. Since none of the respondent's requests can be allowed, the patent has to be revoked under Article 101(2) and (3)(b) EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The patent is revoked.

The Registrar:

The Chairman:



D. Hampe

M. Alvazzi Delfrate

Decision electronically authenticated