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D E C I S I O N
of 23 June 1999

Case Number: T 0894/95 - 3.2.2

Application Number: 88304091.7

Publication Number: 0298585

IPC: A61M 5/28

Language of the proceedings: EN

Title of invention:
Syringe

Patentee:
Duoject Medical Systems Inc.

Opponent:
Schott Glaswerke

Headword:
-

Relevant legal provisions:
EPC Art. 56, 100(b)

Keyword:
"Insufficiency of disclosure (no)"
"Remittal to the first instance"

Decisions cited:
-

Catchword:
-

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Case Number: T 0894/95 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 23 June 1999

Appellant: (Opponent)
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Representative:
-

Respondent: (Proprietor of the patent)
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Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 5 September 1995 rejecting the opposition filed against European patent No. 0 298 585 pursuant to Article 102(2) EPC.

Composition of the Board:

Chairman: W. D. Weiß
Members: D. Valle
J. C. M. De Preter

Summary of Facts and Submissions

I. On 3 November 1995, the appellant lodged an appeal against the decision of the Opposition Division of 5 September 1995 on the rejection of the opposition against the European patent No. 0 298 585 and paid the appeal fee on the same day.

Opposition was filed against the patent as a whole and based on Article 100(a) EPC (lack of novelty and inventive step) and on Article 100(b) EPC (insufficient disclosure).

The Opposition Division held that the subject-matter of the patent as granted was novel and involved an inventive step with respect to the documents

(A10) "Primär Packmittel", Algner, Helbig & Spingler, Wissenschaftliche Verlagsgesellschaft mbH (1984), pages 62 to 82, and

(All) Pharm. Ind. 35 (1973) pages 824 to 829

(A13) DIN 58 366 (Parts 1, April 1979 and Part 5, February 1981)

and that the patent as granted disclosed the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

II. In its grounds of appeal, the appellant cited two new documents

(A14) DE-A-1 910 695 and

(A15) DE-C-0 882 600

in addition to the documents cited during opposition proceedings and maintained its previous objections on the basis of Articles 100(a) and l00(b) EPC.

The respondent submitted with letter of 25 May 1999 a copy of an advertisement originating from the opponent

(A16) advertisement "Just like a vial" by SCHOTT Parenta Systems, in "Pharmaceutical Technology" September 1995.

In a communication issued together with the summons for oral proceedings, the Board drew the attention of the Parties to its intention to discuss documents A14 and A15 at the oral proceedings.

At the oral proceedings, the appellant no longer maintained its novelty objection.

III. Oral proceedings were held on 23 June 1999. At the end of the oral proceedings the requests of the parties were the following:

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

The respondent (patentee) requested that the appeal be dismissed, subsidiarily that the case be remitted to the first instance.

IV. The wording of the Claim 1 as granted is as follows:

"A method of producing a prefilled syringe for administering a pharmaceutical preparation, said syringe comprising a generally cylindrical syringe body (6) having a neck at a neck end, and a side wall terminating in a rim (7) at a rimmed end, at least a component (A) of the preparation filled into the body (6) via the neck end and sealed in the body (6) with an elastomeric closure (5) closing the body at the neck end and secured by a cap (4), and an elastomeric piston (8) at the rimmed end forming a hermetic seal with an inside surface of said side wall, needle means (22) for movement relative to the cap (4) to penetrate the elastomeric closure (5), and plunger means (10) for connection to an outer side (16) of the piston, characterized in that the syringe is produced by associating components including said plunger means (10) and said needle means (22) with a prefilled vial (6) produced by forming said body with a height to diameter ratio such that the body is stable, and so that any outward extent of the rim (7) is insufficient to result in interference such as would cause tipping, when the body is conveyed standing on said rim (7) through equipment for filling and capping pharmaceutical vials; inserting said elastomeric piston (8) wholly within said rimmed end of the body to form a vial (6) open at the neck; and filling said vial through said neck with said pharmaceutical preparation (A), and then applying said elastomeric closure (5) and said cap (4), whilst conveying the vial (6) standing on said rim (7) through equipment for filling and capping pharmaceutical vials."

V. The appellant argued as follows:

- Regarding Article 100(b) EPC

The feature:

"forming said body with a height to diameter ratio such that the body is stable, and so that any outward extent of the rim (7) is insufficient to result in interference such as would cause tipping, when the body is conveyed standing on said rim (7) through equipment for filling and capping pharmaceutical vials"

is merely a purposive statement and does not give any clear teaching in order to perform the invention as claimed. A purposive statement is not the same as disclosing the means to attain that purpose. The patent specification does not contain any piece of information in order to attain through a limited number of routine tests the stated purpose. There is in fact an indefinite number of height to diameter ratios, of rim dimensions and types of filling equipment, so that the person skilled in the art would have to perform an indefinite number of tests until possibly finding a suitable form for the filling equipment.

The description does not disclose in detail anything specific about the filling equipment, but only that it should be "conventional" or "available".

Also the definition of the term "vial" in the description, column 2, lines 26 to 31, as: "rather

squat cylindrical body" in contrast to: "cartridge", does not give any clear technical teaching.

- Regarding the inventive step

The subject-matter of Claim 1 does not involve an inventive step having regard to documents (A10) and (A11).

Document (A10) shows bodies having a height-diameter ratio and a rim such that they can be filled in conventional filling stations for "Injektionsflaschen", see in particular page 66. From this document it is also known to connect a piston rod and needle to the injection container, see page 69, Figure 3.

The filling device of document (A10) is a commercially available, conventional filling station like that cited by the invention, see column 2, line 16 of the patent application.

According to the DIN norm 58366 (A13) the term "Injektionsflasche" refers to a rather squat glass container with a bottom, designed to be filled from the neck. Document (A13) gives the normal dimensions for them.

Document (A11) describes the evolution from the usual "Rekordspritze" to a ready-to-use "Spritzampulle".

Originally - see Figure 1, page 826 - two

different containers were necessary in order to make an injection, one, provided with a piston and a needle for the injection of the substance: the "Rekordspritze", and one for the storing of the substance: the "Glas-Ampulle" (upper left of Figure 1) or the "Rollrandfläschen" (upper right of Figure 1). The "Rollrandfläschen" was obviously filled while standing on its basis. The evolution led to the so-called "Spritzampulle" consisting on a cylindrical glass provided on one basis with an rubber piston and on the opposite basis with a rubber cap and a needle. On page 827, last paragraph it is said that the "Spritzampullen" can be processed in filling and capping machines according to the same principles as the "Rollrandfläschen". The process of course comprises both the filling and the transportation.

- Regarding the newly submitted documents

Documents (A14) and (A15) are relevant because they show that the problem of the invention has already been solved no later than in the year 1969.

VI. The respondent argued as follows:

- Regarding Article 100(b)

The choice of the height to diameter ratio and the rim shape is a mere routine choice. Column 5, line 15 of the description of the patent in suit cites a specific numerical value of the height-width ratio.

Furthermore the term vial is not undefined. The appellant himself shows knowledge of what it means when he in document (A16) advertises his product as being "just like a vial". The body of the syringe according to the invention differs from a conventional vial only by the fact that it is without the bottom and it is provided by a piston, see column 3, line 5 of the description.

- Regarding the inventive step

Document (A10), page 66, Figure 1, refers exclusively to long, thin barrel-shaped ampoules or cartridges designed to be placed into the primary syringe structure (see Figure 1) and having a flange rim at the top so that they can be processed while being suspended from such flanged rim and without standing on its base. Capping is not mentioned at all.

On the contrary, the vial utilized by the invention is a conventional bottle shaped pharmaceutical vial the bottom of which is removed. It forms the body of the syringe and it is not just a container placed inside a syringe body. Page 66 is silent on the height-diameter ratio and the degree of rim protection and as to whether the barrel ampoules are transported free standing through filling and capping machinery.

The problem to be solved starting from a device according to document (A10) consists in improving the existing processing techniques for long cartridges. The solution according to the patent

in suit was to redesign the body so that it can stand stably on its base. Document (A11) does not give any hints in this direction. The last sentence of page 827 does not disclose that the body can be conveyed in a conventional filling machine for vials standing on their bases.

- Regarding the newly submitted documents

Documents (A14) and (A15) are late filed and not relevant and therefore they should not be admitted in the procedure. If the Board intends to introduce such late filed documents into the proceedings, the case should be remitted to the first instance for further prosecution in order to guarantee a judicial review if the patent might be revoked on the basis of the new filed documents.

Reasons for the Decision

1. The appeal is admissible.

2. *Sufficient disclosure*

The purposive statement contained in the claim indicates to the person skilled in the field to chose a height to diameter ratio of the body and a dimension of the rim so that:

1. the body can be filled by conventional filling equipment for vials when standing on said rim, and

2. it is not tipped during operation.

The person skilled in the art, therefore, has sufficiently detailed instructions to choose a conventional machine and to adapt the chosen dimensions of the body, so that the filling is successfully completed. There is no necessity to perform an indefinite number of tests, because a successful approach is indicated. On the contrary the direction of the modifications in order to achieve it are predictable. In particular it is clear that in the case of tipping an increase of the diameter will improve the stability, and a reduction of the rim width will decrease the risk of mutual interference between adjacent containers. A favourable result can be achieved by means of a limited number of routine tests.

Accordingly claim 1 complies with Article 100(b) EPC.

3. *Inventive step*

Document (A10) discloses a method of producing a prefilled syringe (page 66, chapter 2, title) for administering a pharmaceutical preparation, said syringe comprising a generally cylindrical syringe body having a neck at a neck end, and a side wall terminating in a rim at a rimmed end (page 66, Spritzampullen), at least a component of the preparation filled into the body and sealed in the body with an elastomeric closure (rubber, page 66, line 18; see also column 5 of the description of the patent in suit, lines 26 and 44) closing the body at the neck end and secured by a cap (page 68, fourth line from the bottom), and an elastomeric piston (page 66, line 18, page 68, third line from the bottom) forming a hermetic seal with an inside surface of said side wall, needle means (paragraph bridging pages 69, 70) for movement relative to the cap to penetrate the elastomeric closure, and plunger means (page 70, lines 3 to 8) for connection to an outer side of the piston, whereby the syringe is produced by associating components including said plunger means and said needle means with a prefilled container produced by inserting said elastomeric piston wholly within said end of the body to form a container open at the neck and filling said container through said neck with said pharmaceutical preparation, and then applying said elastomeric closure and said cap, whilst conveying the container through conventional equipment for filling and capping pharmaceutical containers (page 66, lines 19, 20). The container of document (A10) may form the syringe body (see page 69, Figure 3, right embodiment) and "capping" is mentioned (see page 68, fourth line from the

bottom).

The fact that the bodies disclosed in document (A10) are filled like "Injektionsflaschen" (see page 66, line 19) implies that they are filled from the top.

The subject-matter of claim 1 differs therefrom essentially by the fact that the body of the container has a height to diameter ratio such that the body is stable when the body is conveyed when standing on said rim through equipment for filling and capping.

The distinguishing feature that the vial is conveyed through the filling machine standing on said rim has the effect of increasing the flexibility of the production line since successive stations can work at their own pace.

This distinguishing feature cannot be derived in an obvious manner from the cited prior art.

Document (A10) (page 66, para. "Spritzampullen") states that "Spritzampullen" are characterised by a "Zylinderampulle mit Bördelrand" as container for the drug. There was common agreement at the oral proceedings that, in the normal technical use of the German language, a "Zylinderampulle" is characterised by a rather slim axially extended cylindrical body as displayed in Figure 3 on page 69. Because of this shape it is not apt to stand stably when resting on its plunger end. It is, therefore, conveyed through the filling and capping stations suspended by the flange ("Bördelrand") surrounding the filling opening. This results in the drawback that these successive stations

have to work at the same pace.

In contrast thereto, an "Injektionsflasche" has a shape and dimensions corresponding to a "vial" within the meaning of the patent in suit (see document A13) and is suited to stand stably on its base. That means, that it may be either conveyed through the filling and capping stations standing on its base or suspended on the top flange in the same equipment which processes the "Zylinderampullen". Having this in mind, the said statement on page 66 of document (A10) and the similar statement on page 827, last paragraph, of document (A11) only makes sense when interpreted as referring to the fact that both containers may be conveyed in equipment while suspended from the top flange.

The fact that in the period between the publication of the document (A11) (1973) and that of document (A10) (1984) there have been no tangible developments towards the improvement suggested by the invention is a further circumstantial indication for the presence of an inventive step.

Consequently, documents (A10) and (A11) either alone or in combination do not refute the fact that the subject-matter of claim 1 involves an inventive step.

4. *Admissibility of the late filed documents and remittal to the first instance*

Documents (A14) and (A15) are prima facie relevant in the sense that they are likely to influence the outcome of the case (see: Case Law of the Boards of Appeal of

the EPO, 1998, page 301, point 2.1 and page 302, first paragraph). Furthermore they have been filed in order to reinforce the line of attack already made before the first instance. They are therefore admitted into the procedure.

Under these circumstances, and also taking in account the request of the respondent, the Board finds it appropriate to remit the case to the first instance for further prosecution in order to guarantee the possibility of a judicial review following the decision of the first instance on the basis of the newly filed documents.

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 for further prosecution

The Registrar: The Chairman

M. Maslin W. D. Weiß