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Bezeichnung der Erfindung:
Title of invention:
Titre de l'invention : Multiple-compartment syringe

Klassifikation / Classification / Classement : A61M5/18

ENTSCHEIDUNG / DECISION

vom / of / du 27 February 1986

Anmelder / Applicant / Demandeur : Duphar International Research B.V.

Patentinhaber / Proprietor of the patent /
Titulaire du brevet :

Einsprechender / Opponent / Opposant :

Stichwort / Headword / Référence :

EPÜ / EPC / CBE Article 52(1), 56
"Inventive Step"
"Long felt want"

Leitsatz / Headnote / Sommaire

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Case Number : T 205 /85

D E C I S I O N
of the Technical Board of Appeal 3.2.1
of 27 February 1986

Appellant : DUPHAR INTERNATIONAL RESEARCH B.V.
C.J. van Houtenlaan 36, NL-1381 CP Weesp

Representative : Swaters, Pieter D., Drs. et at,
Octrooibureau ZOAN B.V. Apollolaan 151, NL-1077 AR Amsterdam

Decision under appeal : **Decision of Examining Division 128 of the European Patent Office dated 29.03.85 refusing European patent application No 82 200 891.8 pursuant to Article 97(1) EPC**

Composition of the Board :

Chairman : M. Huttner
Member : P. Delbeque
Member : G. Paterson

Summary of Facts and Submissions

I. European patent application No. 82 800 891.8, filed on 13 July 1982, claiming priority from a prior Dutch application dated 10 August 1981, and published on 16 February 1983, under publication No. 72 058, was refused by a Decision of the Examining Division 128 of the European Patent Office dated 29 March 1985. The Decision was based on the Claims 1 to 7 received on 29 August 1984.

II. The reason given for the refusal was lack of inventive step, as far as Claim 1 was concerned, in view of GB-A-2 010 681, US-A-3 911 916 and FR-A-2 110 516. The first instance stated further that none of the dependent Claims 2 to 5 and 7 was patentable either, also because of lack of inventive step, having regard to US-A-3 330 282 and GB-A-2 010 681.

As far as independent Claim 6 was concerned the reason given for the refusal was lack of inventive step having regard to the disclosure of GB-A-2 010 681 (Claim 4).

III. On 9 May 1985, the Applicant lodged an Appeal against the Decision of 29 March 1985 and paid the fee within the time limit. The Statement of Grounds was received on 29 June 1985. The Appellant contended that the subject-matter as claimed in Claims 1, 6 and 7 involved an inventive step as required by Articles 52.1 and 56 EPC. He therefore requested that the Decision of the Examining Division be set aside and that European Patent be granted on the basis of the claims on file.

The Appellant also requested oral proceedings if refusal of the application was envisaged.

IV. A summons to oral proceedings together with a Communication was issued on 15 January 1986. In view of the oral proceedings the Appellant introduced by letter dated 31 January 1986 a new Claim 1 which reads as follows :

1. A syringe, comprising a rotationally symmetrical barrel which is open at each end, a piston which is movable in the barrel and seals same, to which piston a piston rod is or can be connected, a sealing stopper the dimensions of which are such that it can be provided sealingly in the opening on the front end of the barrel, a finger grip or means for the connection thereof to the outside of the barrel, a needle holder, comprising (a) a collar which is or can be provided sealingly on the front of the barrel, (b) a neck in which an injection needle is or can be sealingly connected, (c) a hollow shaft between collar and neck, the dimensions of said shaft being such that the space bounded by the inner wall of the shaft and the rear face of the neck has the same or a slightly larger circumference than the inner wall of the barrel, and (d) a passage formed in the inner wall of the shaft and the rear face of the neck past which injection liquid behind the sealing stopper can reach the injection needle during use of the syringe, the syringe being characterized, in order to be used without fundamental changes for injecting two or more than two different injection liquids which may not be in contact with each other for a longer period of time, (i) in that the syringe comprises one or more separating stoppers to be provided in the barrel and movable therein, said separating stopper or stoppers having a circumference that sealingly adjoins the inner wall of the barrel thereby keeping the injection liquids present in the barrel separated from each other prior to use of the syringe, (ii) in that the space in the shaft of the needle holder is slightly longer than the collective

stoppers, so that in the extreme forward position the collective stoppers can fill said space substantially entirely, and (iii) in that the passage in the inner wall of the shaft of the needle holder is slightly longer than the collective stoppers so that in their extreme forward position the collective stoppers do not cover a portion of said passage adjoining the barrel.

The original independent Claim 6 reads as follows :

6. A needle holder for a syringe as claimed in any one of the preceding claims, comprising a collar with which the needle holder can be sealingly connected to the front of a barrel in which a piston and at least two stoppers can beprovided, a neck in which an injection needle can be connected, and a hollow shaft connecting the collar to the neck in a sealing manner, characterized in that the space bounded by the inner wall of the shaft and the rear face of the neck is slightly longer than the collective stoppers to be provided in the barrel and has a slightly larger circumference than the inner wall of the barrel.

V. During the oral proceedings which were held on 27 February 1986, the Appellant made clear the difference in practice between the syringe according to GB-A-2 010 681 which was normally prefilled with one single liquid and normally preassembled, and the syringe according to the European application which was not or not completely assembled and was normally filled by the customer with two or more liquids according to his needs. The customer had the possibility to select the ampoule, the number of stoppers he needed and the corresponding needle holder. This syringe therefore provided a flexible solution in accordance with the customer's needs.

Reasons for the Decision

1. The appeal complies with the requirements of Articles 106-108 and Rule 64 EPC. The appeal is therefore admissible.

2. The question whether there are any formal objections to the current version of the claims and of the description need not be answered since Claim 1 is unallowable on other grounds.

3. After examination of the citations uncovered by the search report and of those introduced during the examination procedure, the Board is satisfied that none of them discloses a syringe including all the features stated in Claim 1. Since this has never been disputed, there is no need for further detailed substantiation of this matter. Therefore, the subject-matter as set out in Claim 1 is novel (Art. 54 EPC).

4. The precharacterizing portion of the new amended independent Claim 1 only comprises features which are also disclosed in combination in GB-A-2 101 681 which, according to both the Board and the Appellant, constitutes the closest prior art.

   A syringe according to the disclosure of this prior patent is of a bipartite construction and is intended to be used for the injection of one single liquid medicament.

5. The object of the invention, according to the Appellant, is firstly to provide a multi-compartment syringe to be used without fundamental changes for injecting two or more different injection liquids which may not be in contact with each other for a longer period of time, and secondly preserving a simple and low cost construction (description page 3, lines 10 to 15).

5.1 Those problems are themselves already known from US-A-3 911 916 according to which a syringe for two or for more than two liquids differs from a conventional one-dose syringe only by the number of separating plugs used and by provision of a needle with a corresponding number of apertures. Furthermore it is an object of that US patent to provide such a syringe which is simple in construction and of low manufacturing costs. No contribution to the inventive merit of the solution can be seen in the formulation of those problems.

Therefore, there has not been a discovery by the Applicant of an unrecognized problem such as could, in some circumstances, give rise to patentable subject-matter.

5.2 Bearing that in mind and starting from the closest known prior art, i.e. GB-A-2 010 681, the solution to the given problem could easily be found, especially having regard to the guidance given by the prior documents dealing with multi-dose syringes, e.g. US-A-3 914 419, which are intended for administering any given number of doses.

Indeed, for providing a multi-dose syringe clearly one or more liquid separating stoppers are needed, and if a separating stopper is used, means are necessarily to be provided to by-pass that stopper as soon as it arrives in its foremost position in order to permit the liquid behind it to be expelled consecutively. Guidance in this respect

was in any event available as part of that state of the art. It was therefore obvious to the skilled person faced with the problem set out above to modify a syringe according to GB-A-2 010 681 so as to arrive at a multi-compartment syringe according to Claim 1 of the application by extending the by-pass accordingly, to accommodate the required number of stoppers.

5.3 During the oral proceedings the Appellant emphasized that there was a need to provide a syringe which is flexible in use, whereby the different constituting elements may be sent to the user, who prior to assembly makes the choice of the number of separating stoppers needed and of the needle holder adopted to accommodate that particular number of stoppers.

However, while the need for multi-dose syringes since about 1970 can be seen from the prior documents, there is no evidence that a need for a flexible multi-dose syringe as just discussed existed much earlier than the priority date. Thus it was not established that flexibility constituted a long-felt need. On the contrary, during the oral proceedings the Appellant referred to a recent new demand from the users. Where the demand previously had been for single dose syringes, which were mostly prefilled and normally preassembled, recently there had been a new demand for multi-dose syringes which were not or not completely assembled and which were to be assembled by the user in accordance with the number of liquids which was needed. That demand had arisen in the period immediately preceding the priority date of the application.

It is correct, as the Appellant argued, that GB-A-2 010 681 is exclusively concerned with a single compartment syringe and therefore contains no express signpost as to how to overcome the disadvantage inherent in the construction of

the pre-assembled syringe, and thus to adopt the route indicated in the European application. On the other hand, the change resulting in the new construction was not a consequence of an inventive effort originating from the Appellant but rather was dictated by a new and recent demand from users coupled with non-inventive modification as discussed above.

Furthermore, the idea of flexibility put forward by the Appellant was already present in US-A-3 911 916, column 6, lines 31-34, where the possibility is mentioned to load pre-packed cartridges provided with two or more medicaments into the barrel prior to injection.

6. For the foregoing reasons, the subject-matter of Claim 1 lacks inventive step as required by Article 56 EPC. Therefore it cannot be allowed having regard to Article 52(1) EPC.

7. Claims 2 to 5 and 7 are dependent on the Claim 1. They are concerned with details of construction which are known in the art. They cannot be maintained either inasmuch as their validity depended on the validity of Claim 1, which as been denied.

8. The independent Claim 6 deals with a needle holder for a syringe as claimed in any one of the Claims 1 to 5.

The Board agrees with the Examining Division that it would be quite obvious for the man skilled in the art that he could use the needle holder according to the prior art document GB-A-2 010 681 in connection with a multiple-compartment syringe and adapt it, as said in point 5.2 above, in order to permit the liquid behind the stoppers to by-pass those stoppers. The subject-matter of that Claim 6

therefore does not involve an inventive step according to Article 56 EPC and cannot be allowable having regard to Article 52(1) EPC.

Order

For these reasons, it is decided:

the appeal against the decision of the Examining Division is dismissed.

The Registrar: The Chairman:

B. A. Norman M. Huttner