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DECISION of 17 August 2000

Case Number: T 0445/00 - 3.2.2

Application Number: 87903026.0

Publication Number: 0413679

A61M 5/32 IPC:

Language of the proceedings: EN

Title of invention: Safety cap syringe

Patentee:

SCHNEIDER MEDICAL TECHNOLOGIES, INC.

Opponent:

Headword:

Relevant legal provisions:

EPC Art. 52(1), 56

Keyword:

"Inventive step (no)"

Decisions cited:

T 0176/84, T 0195/84

Catchword:



Europäisches Patentamt European Patent Office

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Boards of Appeal

Chambres de recours

Case Number: T 0445/00 - 3.2.2

DECISION
of the Technical Board of Appeal 3.2.2
of 17 August 2000

Appellant: SCHNEIDER MEDICAL TECHNOLOGIES, INC.

1718 West Flournoy No. 402 Chicago, IL 60612 (US)

Representative: Goddar, Heinz J., Dr.

FORRESTER & BOEHMERT Franz-Joseph-Strasse 38 D-80801 München (DE)

Decision under appeal: Decision of the Examining Division of the

European Patent Office posted 4 November 1994

refusing European patent application

No. 87 903 026.0 pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: W. D. Weiß

Members: S. S. Chowdhury

M. B. Günzel

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# Summary of Facts and Submissions

I. The present appeal is against the decision of the examining division, dated 4 November 1994, to refuse European patent application No. 87 903 026.0. The division reasoned that the subject-matter of the claims then under consideration lacked inventive step.

Reference was made in the decision to the following documents:

D1: US-A-4 425 120

D2: US-A-4 643 200

II. A notice of appeal was filed by the Appellant (patent applicant) by letter dated 3 January 1995, and the grounds of appeal were filed by letter dated 28 February 1995.

Oral proceedings before the Board took place on 17 August 2000. The Appellant requested that the decision be set aside and a patent be granted on the basis of claims 1 to 3 filed with its letter dated 16 August 2000. As an auxiliary request the Appellant requested that a patent be granted on the basis of claims 1 to 3 filed with its letter dated 13 July 2000.

III. In support of inventive step, the Appellant presented the following arguments: The person skilled in the art would not consider the Document D2 since it related to a different technical field, viz. blood collection apparatus. Moreover, the subject-matter of claim 1 was not derivable from a combination of the Documents D1 and D2, and furthermore, since these documents related to respective apparatus with many differences, it was

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not a straightforward matter to combine them.

IV. The wording of the claim 1 of the main request is as follows:

"A hypodermic syringe for giving injections, comprising:

a hollow barrel (58) having first and second opposite ends;

a plunger slidably movable along and extending from said first barrel end;

a hypodermic needle mounted extending axially outward from said second opposite end of said barrel (58) and being in fluid communication with an interior of said barrel (58);

a sleeve (52) encircling a portion of said barrel (58) and slidably movable between a first position in which said needle projects from said sleeve (52) and a second position, in which said needle being contained within said sleeve (52); and

a rotationally locking engaging means for engagement between said sleeve (52) and said barrel (58) including a longitudinally extending channel (56) and a portion (62, 62) at a first end of said channel (56) and a projection (50) extending into said channel and moving along said channel during sliding movement of said sleeve and interlocking with the circumferentially extending locking means (60, 62),

characterised in that

said rotationally locking engaging means includes a second portion (60, 62) at a second end of said longitudinally extending channel (56) opposite to said first end, said second portion imposing resistance to free movement of the sleeve (52), said projection (50)

forced to remain in said longitudinally extending channel (56) during sliding movement of said sleeve and thereby preventing free rotation of said sleeve (52) relative to said barrel (58);

said longitudinally extending channel (56) being formed in an exterior surface of said barrel (58), and said projection (50) extending inwardly on an interior of said sleeve (52) for movement along said channel (56) or

said longitudinally channel (56) being formed in an interior of said sleeve (52) and said projection (50) extending from an exterior surface of said barrel (58) for movement along said channel (56)."

Claim 1 of the auxiliary request differs from the above claim essentially as follows:

- The locking portions are defined as being circumferentially extending.
- The second locking portion is oriented in the same circumferential direction as the first locking portion (50).
- The second portion of the rotationally locking engaging means are not defined as imposing resistance to free movement of the sleeve.

#### Reasons for the Decision

- 1. The appeal complies with the provisions mentioned in Rule 65(1) EPC and is therefore admissible.
- 2. Amendments

The amendments to claim 1 give rise to formal objections, but these need not be discussed in view of the fact that the claimed hypodermic syringe of both requests does not involve an inventive step.

#### 3. Novelty

This has not been an issue during the examination or appeal procedures and the Board sees no reason to doubt the novelty of the claimed subject-matter.

## 4. Inventive step (main request)

## 4.1 Closest prior art

The present application relates to a hypodermic syringe for giving injections. Hypodermic needles on syringes are generally provided with a protective cap which is removed from the syringe prior to an injection and which is replaced after the hypodermic needle is used to prevent injury from exposed needles. In recapping the hypodermic needle, the exposed needle and cap are moved toward one another by hand, which can result in accidental piercing of the skin by the used needle. This is a serious health hazard to health care workers treating patients with infectious diseases, such as hepatitis or AIDS.

The object of the application is to reduce the risk of an accidental prick from a hypodermic needle.

Document D1 discloses such a hypodermic syringe and also relates to the same problem, as set out in column 1, lines 12 to 28, and represents the closest prior art. This was also the position of the examining

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division and of the appellant.

#### 4.2 The disclosure of Document D1

Document D1 discloses the following features of the first part of claim 1: A hypodermic syringe for giving injections, comprising: a hollow barrel 13 having first and second opposite ends; a plunger 17 slidably movable along and extending from said first barrel end; a hypodermic needle 15 mounted extending axially outward from said second opposite end of said barrel and being in fluid communication with the interior of said barrel; a sleeve 19 encircling a portion of said barrel and being slidably movable between a first position in which said needle projects from said sleeve and a second position, in which said needle is contained within said sleeve; and a rotationally locking engaging means 49 for engagement between said sleeve and said barrel and including a longitudinally extending channel 59 and a circumferentially extending locking portion 61 at a first end of said channel (see column 3, lines 49 to 51) and a projection 47 extending into said channel and moving along said channel during sliding movement of said sleeve and interlocking with the circumferentially extending locking means.

Document D1 also discloses the following features of the characterising part of claim 1:

said rotationally locking engaging means includes a second circumferentially extending locking portion 51, 61, said second locking portion being oriented in the same circumferential direction as the first locking portion, said longitudinal channel being formed in the exterior surface of said barrel, and said projection

extending inwardly from said sleeve for movement along said channel or said longitudinally extending channel being formed in an interior of said sleeve and said projection extending from an exterior surface of said barrel for movement along said channel (see column 2, lines 41 to 43). Also, the first and second portions of the rotationally locking engaging means impose resistance to free movement of the sleeve (see column 3, lines 51 to 55 and column 4, lines 30 to 32).

## 4.3 Technical problem and solution

The presently claimed syringe differs from the syringe of Document D1 by virtue of the following features:

- the second circumferentially extending locking portion is provided at a second end of the longitudinally extending channel [and it engages the same projection as the first circumferentially extending locking portion]
- the projection is forced to remain in the longitudinally extending channel during sliding movement of the sleeve, thereby preventing free rotation of the sleeve relative to the barrel.

The above features have the effect of making the operation of the sleeve user friendly as compared to the sleeve of Document D1. This prior art sleeve may be held captive in each of its two positions in which one of the projections 45, 47 engages one or other of the locking portions 61, but is freely rotatable in any other position. Therefore, when the user disengages the sleeve from one captive position and slides the projection 45 out of one end longitudinal portion 59,

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the risk is present that the sleeve rotates enough to misalign the projection 45 with respect to the other longitudinal portion, and some manipulation of the sleeve is then necessary to realign the two for engagement. This circumstance is clearly undesirable, particularly as situations often arise when injections must be administered urgently in emergencies, or when the user is under stress.

The technical problem that the above distinguishing features of claim 1 solve is, therefore, that of providing a simple user-friendly protective sleeve in a hypodermic syringe.

- 4.4 The recognition of this problem is not considered to make a contribution to inventive step since the problem will become apparent on use of the prior art syringe, and it is a general desideratum to make apparatus simple and user-friendly.
- 4.5 Moreover, these features are disclosed for the same purpose in Document D2. This document relates to the same problem as the application and Document D1, i.e. to prevent users accidentally being stuck with the needle (see column 1, lines 26 to 32).

The needle apparatus of Document 2, for taking blood from a vein, has a cylindrical body 10 with a throughbore 11 and an external groove 19 with circumferential locking portions 20, 21. A sleeve 22 has an internal lug 23 movably engaging the groove 19. The apparatus is supplied in the state where the lug 23 engages the locking portion 20, i.e. is retracted, and the needle 14 projects therefrom (Figure 1). After blood has been collected the sleeve 22 is rotated and the lug 23 moved

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along the groove 19 to engage the locking portion 21, in which position the needle 14 is inside the sleeve 22 and inwardly of a membrane 26, as shown in Figure 2.

Thus, in this apparatus the second circumferentially extending locking portion 21 is provided at a second end of the longitudinally extending channel (groove 19) and it engages the same projection (lug 23) as the first circumferentially extending locking portion, and the projection is forced to remain in the longitudinally extending channel during sliding movement of the sleeve, thereby preventing free rotation of the sleeve relative to the barrel. Therefore, this arrangement is user-friendly in the above sense.

- 4.6 The Document D2, therefore, provides a simple solution to the above technical problem. The application of this user-friendly solution to the user-friendly apparatus of Document D1 would result in the syringe of claim 1 as an obvious combination.
- 4.7 The Appellant's arguments, set out in section III. above, are not valid for the following reasons:

The question of the extent to which neighbouring areas beyond the specific field of the application might be taken into consideration when assessing inventive step, has been discussed thoroughly by the Boards of Appeal, and the decisions T 176/84 (OJ 1986, 50) and T 195/84 (OJ 1986, 121) set out the principles involved. According to T 176/84, when searching for a solution to a problem in a specific technical field, a person skilled in the art would, in addition to considering state of the art in the specific technical field of the

application, look for suggestions in neighbouring fields or a broader general technical filed if the same of similar problems arose, and if he could be expected to be aware of such general fields. T 195/84 added that the state of the art also had to include prior art in a non-specific (general) field dealing with the solution of any general technical problem which the application solved in its specific field.

Applying the above principles in the present case, the fields of hypodermic syringes and blood collection devices are closely related, both being concerned with the insertion of a needle subcutaneously and into a blood vessel. Both these devices are used by the same medical staff and both are confronted with the problem of the risk of an accidental prick from a hypodermic needle. Therefore, the person using the syringe of Document D1 would notice its user-unfriendly feature, and would be aware of the rather more user-friendly apparatus of Document D2, and would be incited to transfer any advantageous features therefrom to the syringe of Document D1.

### 4.8 Inventive step (auxiliary request)

As demonstrated in point 4.2 above, the Document D1 also discloses those features of claim 1 of the auxiliary request not defined in claim 1 of the main request (see section IV. above). Therefore, the syringe of claim 1 of the auxiliary request is equally devoid of inventive step.

#### Order

# For these reasons it is decided that:

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The appeal is dismissed.

The Registrar: The Chairman:

V. Commare W. D. Weiß