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**Datasheet for the decision
of 22 March 2017**

Case Number: T 1955/12 - 3.2.02

Application Number: 03717859.7

Publication Number: 1494740

IPC: A61M5/31

Language of the proceedings: EN

Title of invention:

A SYSTEM FOR MODIFICATION OF A DEVICE AND A DEVICE SUITABLE
FOR MODIFICATION

Patent Proprietor:

Pfizer Health AB

Opponent:

SANOFI-AVENTIS DEUTSCHLAND GmbH

Headword:

Relevant legal provisions:

EPC Art. 100(a)

Keyword:

Novelty - (yes)
Inventive step - (yes)

Decisions cited:

Catchword:



Beschwerdekammern
Boards of Appeal
Chambres de recours

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Case Number: T 1955/12 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 22 March 2017

Appellant: SANOFI-AVENTIS DEUTSCHLAND GmbH
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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted on 3 July 2012 rejecting the opposition filed against European patent No. 1494740 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman E. Dufrasne
Members: P. L. P. Weber
M. Stern

Summary of Facts and Submissions

- I. The appeal of the opponent is against the decision of the Opposition Division, posted on 03 July 2012 to reject the opposition.

The notice of appeal was filed on 4 September 2012 and the appeal fee paid on the same day. The statement setting out the grounds of appeal was filed on 2 November 2012.

- II. Oral proceedings were held on 22 March 2017.

The appellant/opponent requested that the decision be set aside and that the patent be revoked.

The respondent/patent proprietor requested that the appeal be dismissed.

- III. The documents cited in this decision are the following:

E2: WO-A-98/55168

E4: US-B-6338200

E5: WO-A-01/91833

DIN 8593-0.

- IV. Claim 1 of the patent as granted reads as follows:

"An injection device suitable for modification, said injection device comprising:

- a) a housing (1-3) designed or suitable for manual gripping at a handle (3),
- b) a container for a preparation attachable to (6) or enclosed in the housing,
- c) an outlet (4) for the preparation exposed with respect to the housing,

d) a mechanism arranged for moving the preparation at least from the container through the outlet,
characterised in that the device further comprises
e) a set of elements (11, 11'), wherein the elements are different in at least one respect or property and wherein each element has an outer face (19) possessing a structure, configuration and/or a function fulfilling personal requirements of the user and that the housing and the element are mutually adapted to give a releasable attachment,
and further **characterised in that**
the handle has a ridge (9) forming a site or seat to which is attachable a first one of the set of elements (11, 11'), and
in that each element (11, 11') is U-shaped in cross-section, having a curved inner face (12) possessing a configuration substantially conforming to the shape of the handle, said element being adapted to be brought into releasable clamping engagement with the handle (3) in the site or seat (9), and that each element (11, 11') has a length essentially corresponding to the length of said handle (3) and serving as a grip for the injection device."

V. The arguments of the appellant/opponent relevant for the decision can be summarised as follows:

Lack of novelty in view of E5

When the skilled person read in E5 that the covers had to be replaceable, he immediately thought of the standard releasable connections that were part of the common general knowledge (as exemplified for instance in DIN 8593-0) and considered these standard connections to be implicitly disclosed in E5. As one of the standard ways of connecting replaceable parts was

by a clamping connection, the corresponding feature in claim 1 was anticipated.

Lack of inventive step in view of E5

In any case, it was not inventive - again because it was part of the common general knowledge - to design the connection of a replaceable cover as a clamping connection. Therefore, the subject-matter of claim 1 was not inventive over E5 combined with that common general knowledge.

Lack of inventive step in view of a combination of E5 and E2

E2 disclosed an injection pen with a soft touch layer fixed to the basis structure of the pen by mechanical interlocking fasteners. Moreover, the soft touch layers there disclosed were said to be retrofittable, in the form of a sleeve, to existing pens. Therefore, such a soft touch layer had to be releasably connected to the pen basis structure. A clamping connection was moreover suggested by figure 12 showing that the soft touch layer had a U-shape whose branches went beyond the middle of the pen diameter, which was typical for a clamping connection. For these reasons, the skilled person recognised that such a releasable clamping connection was suitable for fixing the cover modules of E5 and arrived in an obvious manner at the subject-matter of claim 1 of the patent as granted.

Lack of inventive step in view of a combination of E5 and E4

The same was true for the releasable sleeve or adapter fixed by clamping to the syringe barrel of the syringe

shown in E4, so that also a combination of E5 with this document rendered the subject-matter of claim 1 obvious.

VI. The respondent/patent proprietor's arguments are essentially those underlying the reasons for this decision as set out below.

Reasons for the Decision

1. The appeal is admissible.
2. The invention concerns a medical injection device having a housing and a handle which can be customised, by a U-shaped element releasably mounted onto the latter, to meet the needs or wishes of all kinds of patients.

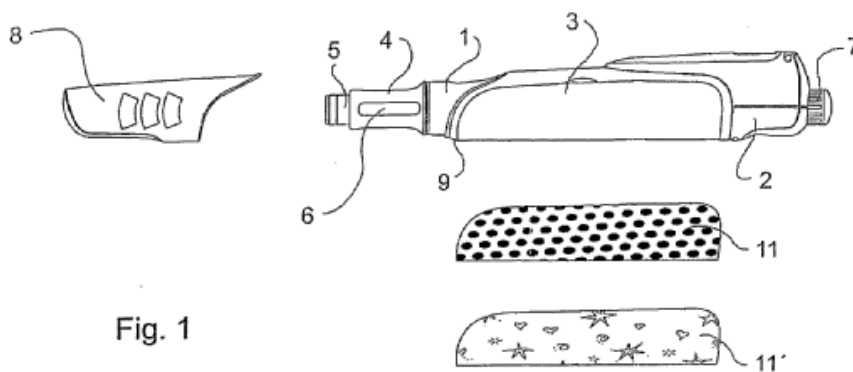


Fig. 1

3. In the present case the Board will concentrate on one feature of the claim, which, in its opinion, is sufficient to justify the decision.
4. Novelty in view of E5

This document describes a modular medication delivery device whose functionalities may be easily adapted to

the particular needs of a given patient in different situations and/or to the needs of different kinds of patients. Several hardware or software replaceable modules can be coupled to a basis module in order to obtain the desired device. There are cover modules 7, 8 and 9 adapted to the different possible combinations of hardware and software modules, and these covers modules may also be replaceable.

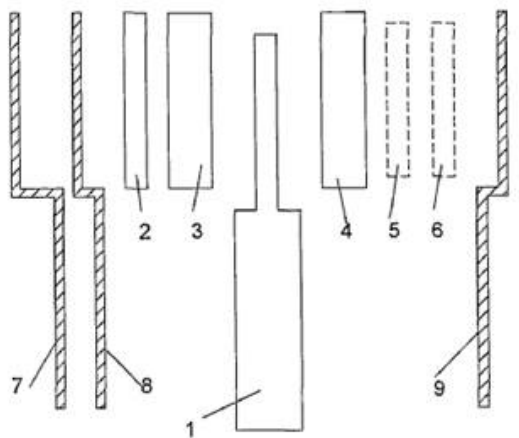


Fig. 1.a

Two paragraphs are interesting in this respect:

Page 9, lines 26 to 30

"When the basis module and the replaceable modules are provided with replaceable covers, it is ensured that the design or look of the medication devices may be adjusted to the instant user wishes, e.g. to match a dress or the like."

Page 13, lines 2 to 13

"Special cover modules for defining the visual impression of the medication delivery device are shown

7, 8, 9. The covers may have different colors, be made of different materials have different surfaces and forms. Covers may be mounted during production so that the device comes with standard or pre-selected covers, which may then later be replaced with other covers according to the user's preferences. The materials of the covers may have different special properties, e. g. elastic or luminescent or water repellent etc. The covers may constitute a water-resistant or watertight enclosure of the medication delivery device."

From the above it follows that when the covers are replaceable, they may be replaced by users according to their preferences, and these covers may have different aesthetic or other properties (luminescent, elastic, water-resistant, etc.).

However, in E5 there is no indication concerning the way the cover modules are attached to themselves or to some basic pen structure or to the combination of hardware and software modules, nor is there any indication that only a site or seat may be covered by such replaceable cover modules. Hence, in the wording of the claim, there is no indication either that the handle is provided with a ridge forming a site or seat to which a first set of covers is attachable, or that the cover is adapted to be brought into releasable clamping engagement with the handle in the site or seat.

At least for this reason, the subject matter of claim 1 is novel in view of E5.

The appellant/opponent considered that the skilled person reading about replaceable covers (i.e. releasable connections) in E5 would consider any kind

of connections disclosed in DIN standard 8593-0, in particular releasable connections including those requiring an elastic deformation for a clamping connection, to be implicitly disclosed. Therefore, for the skilled person the above critical feature was anticipated by E5.

The Board does not share this opinion. Indeed the appellant/opponent himself acknowledged that the said DIN standard discloses many different options for such releasable connections, so that even if the skilled person took it into account, there seems to be no reason why he would specifically associate the releasable clamping connections with the device according to E5. Moreover, a clamping connection does not necessarily require a corresponding ridge, nor does it necessarily define a specific site or seat. For that reason, the specific combination of features as claimed would not, even taking the said standard into account, be directly and unambiguously disclosed by E5.

Therefore, the opposition ground of lack of novelty pursuant to Article 100(a) EPC does not prejudice the maintenance of the patent as granted.

5. Inventive step

5.1 Starting from E5, this document at least discloses neither that the handle is provided with a ridge forming a site or seat to which a first set of covers is attachable, nor that the cover is adapted to be brought into releasable clamping engagement with the handle in the site or seat.

5.2 While the ridge-clamping connection may facilitate the replacement of the covers or cover modules, the

definition of a specific site or seat where the cover module is meant to be attached increases the individualisation possibilities of the pen.

- 5.3 Therefore the Board considers that the objective problem to be solved is to optimise the design for all possible patients, including children, the elderly and disabled patients (patent in suit, column 2, lines 46 to 53; column 3, lines 9 to 25; column 5, lines 50 to 54).

The appellant/opponent considered that the objective problem was to facilitate the replaceability of the cover modules.

In the Board's opinion, this definition of the objective problem fails to take account of the effect of the definition of a specific site or seat by the ridge, and is therefore not appropriate.

- 5.4 While E5 taken alone effectively discloses the use of different replaceable cover-modules adapted to the user's preferences, it contains no teaching encouraging the skilled person to use a ridge to define a specific site or seat, and to use that ridge for a clamping connection for connecting a cover element specifically adapted to that site or seat in order to further individualise the pen. The Board also does not see why such amendments would be obvious for the skilled person. While clamping in itself may be considered to be a known way of connecting elements meant to be connected and disconnected, mere connection by clamping of the cover modules defined in E5 will not lead to the subject-matter of claim 1, because the skilled person would still not have recognised the benefit of defining a specific site or seat with a specific ridge that also

serves for the clamping connection, in order to further individualise the pens of E5.

The subject-matter of claim 1 is thus inventive over E5 combined with the common general knowledge of the skilled person.

5.5 In the Board's opinion, E2 does not suggest the solution of claim 1 either.

E2 concerns a pen for diabetics in which a soft touch layer with a projecting abutment 70 is present over the housing to facilitate grasping or gripping of the pen by the patient.

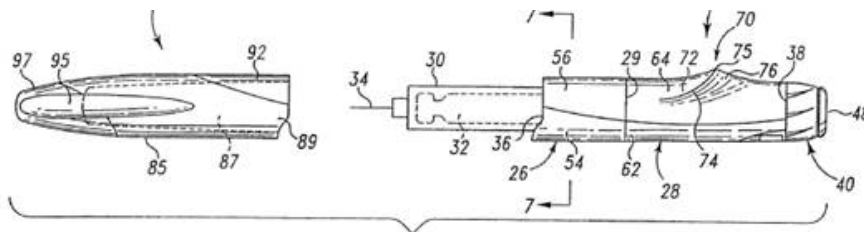


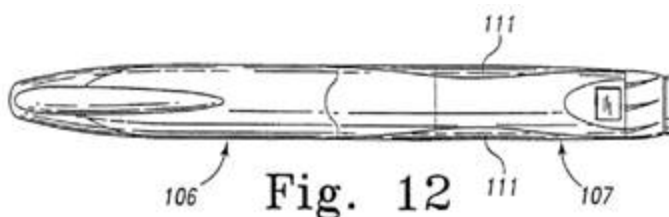
Fig. 1

The soft touch layer and the tubular housing layer of the pen are meant to be permanently fixed together (page 14, line 28 to page 15, line 3: "Housing segments 26 and 28 are each formed via injection molding, preferably via a two-shot molding or co-injection molding process. This fabrication technique permits a chemical bonding to occur between the Triaxs [sic] and Hytrels [sic] materials used for the tubular bases and soft-touch layers, respectively. This chemical bonding ensures a secure interconnection at each of the interfaces of the base and soft-touch layer. The soft touch layers may be attached to their respective bases in alternate fashions. For example, a soft touch layer and base may be adhesively attached together, or

mechanically secured together with interlocking fasteners such as plugs and cooperating recesses integrally molded into the parts." (emphasis added)).

Even though mechanical interlocking fasteners are mentioned as an alternative way for fixing the soft touch layer, there is no teaching whatsoever in E2 that this interconnection should be releasable. On the contrary, the underlined words above stress the need for a permanent connection. This is further expressed in the passage on page 10, line 16 to page 11, line 3, more specifically describing the cross-section shown in Figure 7 of E2 and in particular stating that "Recess 58 allows a thicker layer 56 to be attached to base 54 without having an objectionable step up from base 54 to layer 56, and further aids in preventing delamination of covering 56 from base 54." (emphasis added). Here again the desire to have a firm and permanent connection is clearly apparent.

The appellant/opponent considered that the sentence about alternative ways to carry out the invention on page 18, lines 25 to 28 reading "For example, the soft-touch cover material and/or the finger-engagable axial abutment may be furnished on a sleeve which retrofits existing medication delivery pens." suggested that the soft touch layer had to be replaceable, since it should be retrofittable. This replaceability was emphasised in Figure 12 showing at reference numeral 111 that the soft touch layer surrounded more than half the diameter of the basis pen structure.



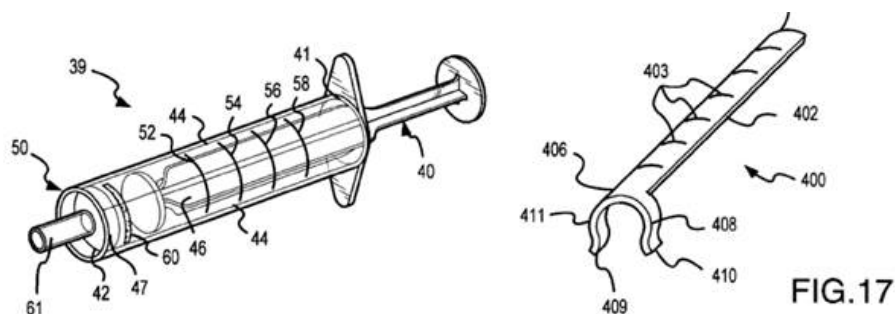
The Board does not share this opinion. In view of the disclosure of E2 as a whole, the above passage means that instead of manufacturing an injection pen with a soft touch layer according to the previously described embodiments, it would be possible to obtain the advantages of the invention on existing pens by fitting a sleeve made of soft touch material and having a finger-engageable abutment on these existing pens. Not only does that not mean that the soft touch layer should be replaceable, but additionally it is also self-evident from the teaching of the document as a whole that such a sleeve would likewise have to be fixed permanently to the existing pen. Figure 12 does not change that finding in any way, since it only concerns the special location of the soft touch layer, not a different way of fixing it.

From the above it follows, first, that it is questionable whether the skilled person would consult document E2 if he wanted to improve the customisation possibilities of the modular pens described in E5, because such customisation is not addressed at all in E2, and second, that a combination of E5 with the teaching of E2 would in any case not lead to the subject-matter of claim 1, because E2 teaches permanently fixing the soft touch layer to the basis structure of the pen, hence, precisely what is not wanted in the invention claimed in the patent in suit.

The subject-matter of claim 1 is thus inventive over a combination of E5 with E2.

5.6 Lastly, E4 does not suggest the subject-matter of claim 1 either. E4 discloses a conventional syringe 40 in combination with a tube-like cover or marking sleeve

50 or in combination with a partial tube-like syringe adapter 400, for indicating a quantity of fluid (depending on the patient) to be drawn into the syringe. The marking sleeve or syringe adapter is slid over the syringe barrel.



Apart from the fact that it is highly doubtful that the skilled person would consult such a document if he wanted to optimise the customisation possibilities of the device according to E5, because it does not address this problem at all, E4 cannot suggest what it does not disclose. The sleeve 50 is a tube open at both ends and said to fit snugly over the barrel of the syringe (column 4, lines 22 to 26), and the syringe adapter 400 is a partial sleeve or cylinder with a collar to be retained on the syringe barrel (column 7, lines 6 to 13), and both have the sole purpose of facilitating the measurement of a dose, nothing more. On the syringe of E4 there is no ridge defining a specific site or seat which should serve as a clamping connection for the sleeve or syringe adapter disclosed therein. Hence, this document cannot suggest these latter features.

The subject-matter of claim 1 is thus inventive over a combination of E5 with E4.

5.7 Therefore, the opposition ground of lack of inventive step pursuant to Article 100(a) EPC does not prejudice the maintenance of the patent as granted.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



B. Atienza Vivancos

E. Dufrasne

Decision electronically authenticated