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Datasheet for the decision of 7 July 2022

Case Number: T 0683/19 - 3.2.05

Application Number: 05704999.1

Publication Number: 1701831

IPC: B29C45/00

Language of the proceedings: EN

Title of invention:
Needle protection device with gauge specific color coding and method for manufacturing thereof

Patent Proprietor:
Smiths Medical ASD, Inc.

Opponent:
Ehlers, Jochen

Relevant legal provisions:
EPC Art. 56, 100(a), 111(1)
RPBA Art. 12(4)
RPBA 2020 Art. 11

Keyword:
Inventive step (main request, auxiliary request I: no)
Admittance of document D19 (yes)
Admittance of auxiliary request II (yes)
Remittal to the opposition division (yes)

Decisions cited:
G 0009/92, G 0004/93, T 1652/08, T 617/16, T 2049/16

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Case Number: T 0683/19 - 3.2.05

D E C I S I O N
of Technical Board of Appeal 3.2.05
of 7 July 2022

Appellant: (Patent Proprietor)	Smiths Medical ASD, Inc. 160 Weymouth Street Rockland, MA 02370 (US)
Representative:	Bernhard Thum Thum & Partner Thum Mötsch Weickert Patentanwälte PartG mbB Siebertstr. 6 81675 München (DE)
Respondent: (Opponent)	Jochen Ehlers Eisenführ Speiser Patentanwälte Rechtsanwälte PartGmbB Johannes-Brahms-Platz 1 20355 Hamburg (DE)
Representative:	Eisenführ Speiser Patentanwälte Rechtsanwälte PartGmbB Johannes-Brahms-Platz 1 20355 Hamburg (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 21 December 2018 concerning maintenance of the European Patent No. 1701831 in amended form.**

Composition of the Board:

Chairman	P. Lanz
Members:	O. Randl
	T. Karamanli

Summary of Facts and Submissions

I. The patent proprietor filed an appeal against the decision of the opposition division which held that European patent No. 1 701 831 ("the patent") can be maintained on the basis of the version of auxiliary request V then on file.

II. The opposition division concluded that the subject-matter of claims 1 and 8 of the main request (patent as granted) and of auxiliary request I did not involve an inventive step. Auxiliary requests II to IV were not admitted. Auxiliary request V, however, was found to comply with all the requirements of the EPC.

III. Among the documents cited by the opposition division, the following are relevant for the appeal proceedings:

D2 US 2003/0036732 A1
D3 US 5,188,611
D4 British standard BS 7128:1993 / ISO 6009:1992 "Specification for colour coding of hypodermic needles for single use", second edition (February 1993)
D5 International standard ISO 7864 "Sterile hypodermic needles for single use", third edition (15 May 1993)
D8 US RE37,110 E
D18 US 2001/053886 A1
D19 US 5,490,841
D21 EP 0 702 973 A2
E2 Brochure "Portex® Needle-Pro® Needle Protection Devices for Hypodermic Injections" (11/02)
E3 Instruction leaflet "Hypodermic Needle-Pro® Needle" in different languages

E4 Brochure "Sharps Safety Products Index" (9/03)
E8 EPCO sales brochure "Multi-shot and Co-injection" (2003)

IV. The oral proceedings before the board took place on 7 July 2022.

V. The appellant (patent proprietor) requested that the decision under appeal be set aside and that the patent be maintained as granted (main request), or, alternatively, that the decision under appeal be set aside and that the patent be maintained as amended on the basis of one of auxiliary requests I to VI filed during the proceedings before the department of first instance.

The respondent (opponent) requested that the appeal be dismissed.

VI. Claims 1 and 8 of the patent as granted (main request) read as follows (the feature references used by the opposition division have been added in square brackets):

"1. [**1.1**] A method of manufacturing a needle device, comprising the steps of:
[**1.2**] a) selecting a needle (12) having a particular gauge;
[**1.4a**] b) adding a specific color that corresponds to the particular gauge to a molding material;
[**1.3**] c) injection molding a needle assembly (2) having a base (4) and a needle protection housing (6) pivotable relative to said base from said molding material [**1.4b**] so that said base and housing having the same specific color, [**1.5a**] said base including a

needle hub (10) having a luer end (16) connectable to a syringe (48);
d) attaching said needle (12) to said base (4),
[**1.6**] said needle (12) adapted to be covered by said housing (6) when said housing (6) is pivoted to a position in alignment along the longitudinal axis of said base; and
[**1.8**] e) covering said needle (12) with a needle sheath (26) to prevent contamination of said needle before use;
[**1.7**] wherein since said specific color corresponds to said particular gauge of said needle, the gauge of said needle can be determined by the colour of said needle assembly."

"8. [**8.1**] A needle device, comprising:
[**8.2**] a needle (12, 56) having a particular gauge,
[**8.3**] an assembly (2, 66) having a base (4, 68) and a needle protection housing (6, 66) pivotable relative to said base formed from a molding material, [**8.4a**] said molding material having added thereto a specific color pigmentation pre-assigned to correspond to the particular gauge of said needle, [**8.4b**] said base and said housing each having said specific color,
[**8.5a**] said needle extending from said base (4) or
[**8.5b**] from a syringe (48) to which said base is fitted, [**8.6**] said needle adapted to be covered by said housing when said housing is pivoted to a position in alignment along the longitudinal axis (22, 82) of said base, [**8.7**] wherein the gauge of said needle can be ascertained by looking at the color of the base and the housing of said assembly."

Claim 1 of auxiliary request I differs from claim 1 as granted in that

- in feature 1.4b, the word "having" is replaced by the word "have",
- in feature 1.5a, the word "having" is replaced by the conjunction "and", the reference "(12)" after the first occurrence of "said needle" is deleted and the words "said base" are replaced by "the needle hub (10) of said base",
- in feature 1.8, the reference "(12)" after the words "said needle" is deleted and the words "by fitting the needle sheath (26) to the needle hub (10)" are inserted before the words "to prevent",
- the following feature is inserted after feature 1.8: "[**1.8b**] there being but a small portion of the needle hub (10) that may be viewed by a user after the needle sheath (26) is fitted to the needle hub (10)", and
- in feature 1.7, the words "the base (4) and the housing (6) of" are inserted before the words "said needle assembly".

Claim 8 of auxiliary request I differs from claim 1 as granted in that

- in feature 8.5a, "said base" is replaced by "a needle hub (10) of said base",
- in feature 8.5b, "a syringe" is replaced by "a needle hub (54) at a syringe",
- the following features are added after feature 8.5b: "[**8.8**] a needle sheath (26, 64) fitted to the needle hub (10, 54) to cover said needle (12, 56) to prevent contamination of said needle (10,54) before use, [**8.9**] wherein when the needle sheath (26) is fitted to the needle hub (10) at said base (4) to cover said needle (12), there is but a small portion of the needle hub (10) at said base (4) that may be viewed by a user, and

[**8.10**] wherein when said needle sheath (64) is fitted to the needle hub (54) at said syringe (48) to cover said needle (56), the needle hub (54) is covered by said needle sheath (64)",

- in feature 8.6, the words "said needle adapted" are replaced by "said needle (12, 56) further being adapted", and the words "said housing" are replaced by "said housing (6, 66) after the removal of said needle sheath (26, 64)", and
- in feature 8.7, the words "the base and the housing" are replaced by "the base (4, 68) and the housing (6, 66)".

Claim 1 of auxiliary request II differs from claim 1 of auxiliary request I in that in feature 1.8 the words "covering said needle with a needle sheath (26) by fitting the needle sheath (26) to the needle hub (10)" are replaced by "mating a needle sheath (26) to the needle hub (10) by frictional contact with fins (10a) that extend along the length of the needle hub (10) to cover said needle with the needle sheath (26)".

Claim 8 of auxiliary request II differs from claim 8 of auxiliary request I in that in feature 8.8 the words "fitted to the needle hub (10, 54)" are replaced by "mated to the needle hub (10, 54) by frictional contact with fins (10a) that extend along the length of the needle hub (10)".

VII. The submissions of the parties, where relevant to the decision, can be summarised as follows:

(a) Main request: inventive step of the subject-matter of granted claim 8 in view of a combination of documents D3 and D5 (ground for opposition under Articles 100(a) and 56 EPC)

(i) Appellant (patent proprietor)

Document D3 as the starting point

According to G-VII, 5.1 of the Guidelines for Examination, an opponent cannot freely develop as many inventive step attacks as it wishes. Rather, only the most promising starting point for a development leading to the invention may be considered the closest prior art. Only document D2 discloses the use of colour coding to determine the needle gauge (see paragraph [0021] of document D2). Document D3 does not mention colour coding and therefore should not be considered the closest prior art.

Differences

If document D3 is considered the closest prior art, the subject-matter of claim 8 differs from the disclosure of document D3 in features 8.4a, 8.4b and 8.7.

Objective technical problem (OTP)

The claimed device has the advantage over the needle device of document D3 that the practitioner can readily determine the needle gauge without having to directly look at the needle. This improves patient safety because the practitioner will always use the correct

needle size (see paragraph [0004] of the patent). Thus, the OTP is the provision of a safer needle device. The opposition division's formulation of the OTP (providing a needle safety device whose needle gauge is more easily identifiable) is inappropriate because it contains a pointer to the solution. This formulation is based on paragraph [0009] of the patent, but in fact the objective technical problem is to be formulated without knowledge of the invention.

Non-obviousness of the solution

Document D3 discloses that the base and the housing can be made as integral parts and injection-moulded as one piece. As there is no suggestion of colour coding the gauge of the needle in document D3, the skilled person would not have had any incentive to consider document D5.

Document D5 is an ISO standard. The skilled person considering this document would have adhered to its teaching and would not have deviated from it in any way. Document D5 teaches that the gauge of hypodermic needles can "be identified by colour coding in accordance with ISO 6009 applied to the unit container and/or part of the needle assembly such as the needle hub or the sheath" (see item 8 of document D5). Thus, document D5 teaches that colour coding may be applied to the unit container and/or the needle assembly, which, as shown in Fig. 1, includes the needle hub 1, the needle 3, the adhesive 2 that glues the needle to the hub, and the sheath 4. If the skilled person had coloured the hub and "accidentally" also the housing (as the parts are integrally moulded from the same coloured material), they would have realised that this is different from the teaching of document D5.

There are many reasons why the hypothetical combination of documents D3 and D5 would have failed to render the claimed invention obvious to the skilled person:

- Document D3 does not disclose colour coding, nor does its device have a sheath according to claim 8. The longitudinal member 21 is not a sheath.
- Document D5 only explicitly teaches colouring the hub or the sheath and the packaging but not the housing. There is no reference to a housing in document D5. So while the skilled person *could* have coloured both parts disclosed in document D3, they *would* not have done so, because there is no such teaching.
- The teaching of document D5 concerning the pigmentation of the sheath is not mandatory (i.e. the skilled person would have had to choose this option) and only concerns *separate* needle sheaths.
- Even single pieces can be injection moulded having several colours (see document E8).
- In document D5, the colour might simply be applied onto the surface of the hub or sheath (e.g. by printing), as in document D2.
- Documents E2 to E4 show that as of 2003, document D5 was implemented by colour codes on packages.
- Document E3 also provides evidence that the unitary colour of the housing and base of the devices in a product line would have been used to brand them.

Such instant colour coding is a simple yet elegant invention. Notwithstanding its simplicity and elegance, it has not been considered before. The invention is obvious only in hindsight, in view of the disclosure of the invention.

(ii) Respondent (opponent)

Document D3 as the starting point

Documents D2, D3 and D8 relate to the same purpose, deal with needle devices and disclose the same features as the opposed claims. They constitute equally valid starting points. The opposition division concluded that the subject-matter of claim 8 does not involve an inventive step over document D3 in combination with document D5. Consequently, document D2 cannot be "closer" than document D3. The Guidelines explicitly allow for the application of the problem-solution approach from several starting points if they are equally valid springboards.

Differences

Document D3 relates to a device comprising a base/hub with a needle. A longitudinal member is attached to the base by a hinge. The housing and the hinge are co-moulded (see col. 6, lines 23 to 27). Fig. 3A shows the needle protection device. The needle is covered by the housing 21 when the housing is pivoted in the longitudinal direction. Thus, document D3 discloses all of the features of claim 8 except features 8.4a, 8.4b and 8.7.

Objective technical problem

The formulation proposed by the appellant is much too broad. It does not match the nature of the distinguishing features. The technical contribution made by the distinguishing features is not safety, which is not mentioned in the patent, but rather better

identification of the needle type. The correct objective technical problem is to provide easier identification of the needle gauge. This formulation does not comprise a pointer to the solution. Colour coding as such was known in the art for needle identification; the core of the invention lies in what exactly is colour-coded.

Obviousness

The person skilled in the art would have considered document D5 when seeking to solve the objective technical problem because they would have been familiar with this standard. Document D5 discloses that colour coding is "applied to the unit container and/or part of the needle assembly such as the needle hub or the sheath" (see item 8). It is also disclosed that the hub and the sheath are made of pigmented material (see items 9.2 and 10). Thus, in document D3 the hub and the housing are one injection-moulded piece. As document D5 requires the hub to be made of pigmented material, the housing would be of the same colour as the hub. Consequently, the skilled person would have arrived at the claimed solution.

(b) Admission of document D19

(i) Appellant (patent proprietor)

Document D19 was filed in the opposition proceedings two weeks before the first-instance oral proceedings. The attack based on document D19 was only substantiated during the oral proceedings. The opposition division admitted document D19 because it considered the document "*prima facie* more relevant to the subject matter of Aux I" (see point 20.3 of the decision). By

acting in this way, the opposition division exceeded the limits of its discretion. The relevant criterion is not whether a document is more relevant than a previously-filed document, but rather whether it is *prima facie* relevant for the outcome of the case (see T 1652/08, point 3.4 of the Reasons). *Prima facie* relevance is ascertained on the face of the facts, i.e. with little investigative effort. Document D19 is not *prima facie* relevant in this sense. Document D19 was admitted into the proceedings at this late stage because it discloses feature 8.9. This feature was known from the claims as granted and there was an abundance of documents already filed within the opposition period showing a sheath not completely covering a small portion of the hub. Thus, document D19 did not go beyond the evidence already on file at that time. The decision to admit document D19 was based on the wrong principles. Therefore, the board should review this decision and disregard document D19.

(ii) Respondent (opponent)

The opposition division admitted document D19 into the proceedings because it is *prima facie* relevant to the amendments introduced with auxiliary request I. It was filed two weeks before the first-instance oral proceedings, as a direct reaction to the filing of auxiliary request I. Its filing was justified because it discloses feature 8.9. The appellant had enough time to study the document. The opposition division exercised its discretion based on the right principles (*prima facie* relevance) and in accordance with the EPC. According to established jurisprudence, a board reviewing the opposition division's exercise of discretion can only examine whether the opposition division applied the right criteria and in a reasonable

way. This was indeed the case. Therefore, the admission of document D19 cannot be challenged.

(c) Auxiliary request I: inventive step of the subject-matter of claim 8 in view of a combination of documents D19 and D5 (Article 56 EPC)

(i) Appellant (patent proprietor)

Document D19 as the starting point

Document D19 is not appropriate as the closest prior art. It does not mention colour coding. The argument that document D19 is more relevant with respect to the additional feature of claim 8 is based on hindsight. Document D2 should be considered the closest prior art. When this document is used as the starting point, the subject-matter of the claims is inventive.

Disclosure of document D19

Fig. 5 of document D19 discloses a sheath device including a housing 12, a cover sheath 42, a needle 40 and a base 36. The sheath is attached to a small hub. In the context of the embodiment of Fig. 4, it is said that the housing 12 is attached to hinge 14, preferably by moulding (see col. 6, second paragraph). The reference to moulding is general and does not necessarily mean integral moulding. In col. 6, lines 30 to 32, a thread connection is disclosed. Friction fit is mentioned in col. 6, lines 32 to 34. In the context of the embodiment of Fig. 5 (see col. 7, lines 10 to 12), "friction fit, adhesive attachment, ultrasonic welding or a combination thereof" is mentioned. Although this sentence refers to the way the needle is fixed to the base, the passage offers a definition of

what is meant by "attached". The connection of the housing and base in the embodiment of Fig. 5 is only described as "attached". One-piece injection moulding is not clearly and unambiguously disclosed. Therefore, in order to arrive at the claimed invention, the skilled person would have had to take a first step by attaching through one-piece injection moulding. In a second step, they would have had to choose document D5. Having taken this step, the skilled person could have coloured the sheath 42 or the hub. Colouring the attached housing would have required yet another step. There was no reason to take this step. Rather, the skilled person would have coloured the sheath.
In summary, the claimed subject-matter involves an inventive step because in order to obtain a device encompassed by the claims, the skilled person would have had to make a number of choices, without having any incentive to do so.

(ii) Respondent (opponent)

Document D19 as the starting point

Document D19 discloses a needle device comprising a housing 12 and a needle sheath 42. The subject-matter of claim 1 thus differs from the disclosure of document D19 by the same features, 1.4 and 1.7, as claim 8. Document D19 also discloses the feature of "a small portion of the needle hub that may be viewed" in Fig. 5. Thus, document D19 is highly relevant for the examination of inventive step. The opposition division was right not to consider document D2 as the starting point because document D19 already renders the claimed subject-matter obvious.

Disclosure of document D19

Document D19 relates to a safety sheath device best described by Fig. 4 and Fig. 5 and col. 6, lines 10 to 30. The needle device of document D19 has a housing and a hinge 14 moulded with the housing. The luer fitting is also integrally moulded, so that the device is one integrally-moulded unit. It is not correct that in the embodiment of Fig. 5 the housing is attached by adhesive. Both occurrences of the word "adhesive" in document D19 (see col. 7, line 11, and col. 6, line 34) refer to the way in which the needle is attached to the base. Moreover, it is said with respect to the embodiments of Fig. 4 and Fig. 5 that the housing 12 and the base 36 are in an open orientation "during molding". This would not make sense if they were moulded separately and attached to each other in a distinct step. Thus, the attachment must be obtained by moulding. The embodiment of Fig. 4 is described as being preferably obtained by moulding (see col. 6, starting at line 10). Thus, moulding is the preferred way of attaching. No other way of attaching is mentioned.

Objective technical problem (OTP)

The distinguishing features 8.4a, 8.4b and 8.7 solve the problem of providing a needle safety device with easier identification of the needle gauge.

Obviousness for the skilled person

The skilled person attempting to solve the OTP would have recognised that the colour code of the needle hub is partially covered by the needle sheath (see Fig. 5). The skilled person would have considered document D5

since it relates to the colour coding of the hub. They would have recognised that the sheath covers the colour code of the needle hub and would have applied colour coding to the needle device. Document D5 would have pointed the skilled person in the direction of pigmenting the moulding material and since the device of document D19 is integrally moulded, the skilled person could and would have arrived at the claimed solution. Therefore, the subject-matter of claims 1 and 8 lacks inventive step over document D19 in combination with document D5.

(d) Auxiliary request II: admittance

(i) Appellant (patent proprietor)

Auxiliary request II was filed during the first-instance oral proceedings in reaction to the admittance of document D19 at such a late stage and in view of the late substantiation of the attack based on document D19. The amendments are based on paragraph [0025] as well as on Fig. 1 and Fig. 2 of the application as filed. The opposition division refused to admit auxiliary request II because "it introduces a feature that was not part of the granted claims and that is diverging from the invention" (see point 23.3 of the decision under appeal). The new feature does not diverge from the invention. The claims of auxiliary request II further define the configuration of the needle sheath in order for it to properly mate to the needle hub. This further improves the safety of the claimed needle device. The opposition division applied two different standards when assessing the admittance of document D19 and auxiliary request II. The patent proprietor's right to be heard was infringed: according to E-III, 8.6, fifth paragraph, of the Guidelines,

"where the opponent files, before the indicated date, pertinent new material, the patent proprietor must be given a chance to present his comments and submit amendments (Art. 113(1))" (emphasis added). The substantive argumentation based on document D19 was provided by the opponent for the first time during the oral proceedings. Thus, the patent proprietor could only properly react during the oral proceedings. The respondent's argument based on the word "corresponding" in point E-V, 2.2 of the Guidelines is unpersuasive. The term "corresponding" should be understood as "in reaction". Whether the amendment is allowable or not is a different matter. The amendment is not random; it addresses the questions of novelty and inventive step. The diameter of the needle hub in Fig. 5 of document D19 is barely visible. The fins add to the volume and to the visibility of the colour. Moreover, a single sheath size can be used for every needle size without any adaptation. There was no need to file the request earlier because it was not clear that the opposition division would admit late-filed document D19. The Guidelines made clear that the patent proprietor would be allowed to file a new request if the document was admitted. As document D19 does not disclose the fins as claimed, the subject-matter of the claims as amended was not *prima facie* unallowable.

(ii) Respondent (opponent)

The opposition division was right not to admit auxiliary request II. As the appellant was allowed to file auxiliary request II, its right to be heard was not infringed. Indeed, the patent proprietor also filed auxiliary requests III to V to overcome the objections that had been made. The decision not to admit auxiliary request II into the proceedings was correct because the

newly defined subject-matter does not constitute a convergent development of the subject-matter which formed the subject of examination (see H-II, 2.7.1 of the Guidelines). The opposition division applied the correct standard when assessing the admissibility of auxiliary request II. Therefore, its exercise of discretion should not be reviewed. The opposition division also applied the right criteria when assessing the admissibility of auxiliary request II. The amendment introduced a new feature unrelated to the purpose of the patent. The new feature does not contribute to needle safety. Moreover, the description is completely silent on the effect of a frictional fitting. E-V, 2.2 of the Guidelines refers to a "corresponding amendment". The opposition division interpreted "corresponding" as "corresponding to the way in which the opponent amended its case". Based on this understanding, the exercise of the opposition division's discretion was legitimate. An arbitrary amendment does not qualify as "corresponding". Moreover, some of the new prior art documents admitted by the opposition division (documents D18 and D21) clearly disclose fins for frictional contact to hold the sheath. Thus, the amendment cannot qualify as a response to the admission of these documents. The subject-matter of the claims of auxiliary request II is *prima facie* not inventive, in particular because the newly added feature has no synergy with the remaining distinguishing features. Although the new prior art documents had been filed two weeks ahead of the oral proceedings, the patent proprietor only filed auxiliary request II at 4 p.m. on the day of the oral proceedings. The request could have been filed before the oral proceedings or at the beginning of the oral proceedings, if only as a precautionary measure. However, the patent proprietor deliberately held back

the request. When exercising its own discretion pursuant to Article 12(4) RPBA 2007, the board needs to keep in mind that it is setting case law and a broad interpretation of this discretion (i.e. that any random amendment is acceptable) would open the door very wide to tactical abuse. In order to prevent such abuse, requiring some degree of "correspondence" between the newly added prior art and the amendment is justified.

(e) Remittal to the opposition division

(i) Appellant (patent proprietor)

The case should not be remitted to the opposition division. The appellant made its case, including regarding compliance with Article 123(2) EPC and inventive step, in its statement of grounds of appeal (see pages 25 to 27) and on page 16ff of its written submission filed on 9 October 2019. The respondent also made its case (see pages 21 to 23 of its reply to the statement of grounds of appeal and page 10 of its written submission filed on 6 April 2020). The parties had more than two years to consider the allowability of auxiliary request II. The board should also take into account the remaining lifetime of the patent.

(ii) Respondent (opponent)

The case should be remitted to the opposition division.

Reasons for the Decision

1. The principle of prohibition of *reformatio in peius*

As the patent proprietor is the sole appellant, the principle of prohibition of *reformatio in peius* applies (see decisions G 9/92 and G 4/93, OJ EPO 1994, 875). This principle protects the patent proprietor as sole appellant from being put in a worse position than it was in before the appeal. The patent maintained as amended according to auxiliary request V, which was considered by the opposition division in its interlocutory decision to meet the requirements of the EPC, cannot therefore be objected to in the appeal proceedings. The board has only the power to review the appellant's main request and auxiliary requests I to IV, which comprise claims that are less limited than those of the patent maintained as amended according to auxiliary request V.

2. Main request: inventive step of the subject-matter of granted claim 8 in view of a combination of documents D3 and D5 (ground for opposition under Articles 100(a) and 56 EPC)

2.1 Disclosure of document D3

Document D3 discloses safety sheaths for needles and other sharp instruments and tools (see the title). The needle device comprises a needle 40 having a particular gauge, an assembly having a base integral with the hub 23 and a needle protection housing 21 pivotable relative to said base formed from a moulding

material. The needle extends from the base and is covered by the housing when the housing is pivoted to a position in alignment along the longitudinal axis of the base (see Fig. 3A).

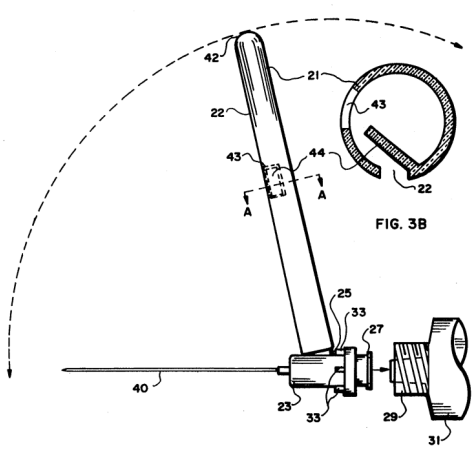


FIG. 3B

FIG. 3A

The needle protection housing 21 and the needle hub 23 are preferably fabricated in one piece from injection-moulded plastic (see col. 6, lines 22 to 27).

2.2 Differences

In point 17.4 of the decision under appeal, the opposition division concluded that the subject-matter of claim 8 differed from the disclosure of document D3 by features 8.4a (a specific colour pigmentation pre-assigned to correspond to the particular gauge of said needle is added to the moulding material), 8.4b (the base and the housing each have the specific colour) and 8.7 (the gauge of the needle can be ascertained by looking at the colour of the base and the housing of said assembly). This finding was not contested by the parties.

2.3 Objective technical problem

The technical effect of the distinguishing features is discussed in paragraph [0009] of the patent.

> "*The present invention has the advantage that, to enable a user to readily determine the needle gauge of a needle assembly that has a housing attached to a base or a needle hub to which the needle is attached, during the manufacturing process, colour pigmentation that is specific to the gauge of the needle is added to the mold material, which most likely would be a plastics material such as polypropylene. With the mold material having the colour that corresponds to the gauge of the needle in accordance with the ISO (International Standard Organisation) standard, a user could readily pick out from among a plurality of needle assemblies the particular gauge of needle she wants to use. For example, a needle assembly with both the base and the housing being black would signify to the user that it is a 22 gauge (22G) needle, while a blue needle assembly would indicate to the user a 23G needle is in that blue needle assembly*."

Based on this disclosure, the opposition division formulated the objective technical problem as follows: "to provide a needle safety device of which the needle gauge is more easily identifiable". The respondent also adopted this formulation. The appellant favoured a different formulation, namely "the provision of a safer needle device". According to the appellant, the problem solved is not only the identification of the needle gauge, but also the improvement of patient safety.

The board has decided not to adopt this alternative formulation for several reasons. First, the patent is not concerned with patient safety. Second, paragraph [0009] comprises a clear statement of what the patent drafter considered to be the technical effect of the distinguishing features. Third, the objection that the opposition division's formulation of the objective technical problem contains a pointer to the claimed solution is unfounded because colouring the base and the housing is by no means the only way of making the needle gauge more easily identifiable.

Consequently, the board has adopted the opposition division's formulation of the objective technical problem.

2.4 Obviousness for the skilled person

The opposition division argued as follows:

> "*A skilled person would find a hint to solve this problem by looking to documents D4/D5. Document D5 on page 2 even mentions that ISO 6009 shall also be applied "..to the unit container and/or part of the needle assembly such as the needle hub or the sheath". The combination of documents D3 and D4/D5 would therefore result in the base and the housing having the same specific colour as in D3 the base and the housing are integral parts and injection moulded as one piece. Taking into account the arguments of the patent proprietor based on documents E1-E8, the* [opposition division] *fails to see why a skilled person would not arrive at the subject matter claimed in claim 8 when looking at D4/D5 starting from D3. Claim 8 is thus not*

inventive over D3&D4/D5" (see point 17.4 of the decision under appeal).

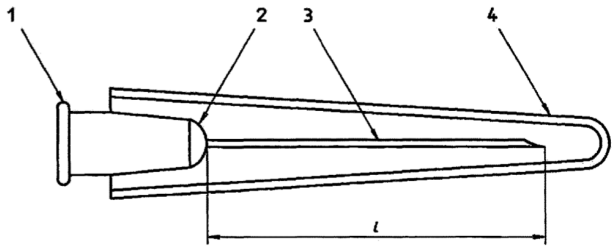
The board has also reached the conclusion that the subject-matter of claim 8 lacks inventive step over the combination of documents D3 and D5 for the following reasons:

Document D5 is an international standard concerning sterile hypodermic needles for single use. The skilled person would have been aware of this standard, as argued by the respondent.

Colour coding is discussed in item 8 of document D5:

"... *The nominal outside diameter of hypodermic needles shall be identified by colour coding in accordance with ISO 6009 applied to the unit container and/or part of the needle assembly such as the needle hub or the sheath...*" (underlining added by the board).

Fig. 1 of document D5 shows these elements:



Key

1 Hub
2 Jointing medium
3 Needle tube
4 Sheath

Figure 1 — Example of typical hypodermic needle and sheath for single use

The board shares the respondent's view that the skilled person seeking to provide a needle safety device with a

more easily identifiable needle gauge would have considered document D5 and would have been taught by this document that identification can be facilitated by means of colour coding on the needle or its packaging, and in particular on parts of the needle assembly such as the needle hub or the sheath.

As the housing and the hub (and the base integral with the hub) are obtained by one-piece injection moulding in document D3, it would have been an obvious choice to colour them by adding a specific pigmentation to the moulding material. Since the purpose of the colour coding is the identification of the nominal outside diameter (i.e. the gauge) of the needle, this can be ascertained from the colour of the base and the housing of the assembly.

The fact that document D5 teaches applying colour coding to the "needle hub or the sheath" is not decisive, because there is no reason to believe that this "or" is exclusive and because applying the same colour to both is the most obvious way of applying the colour to these elements if they are obtained by one-piece injection moulding as in document D3.

None of the counter-arguments raised by the appellant has convinced the board. The reasons for this are as follows:

2.4.1 Counter-argument 1: No suggestion in document D3

The argument that document D3 does not suggest colour coding of the gauge of the needle is irrelevant. The document used as the starting point for the examination of inventive step does not have to make any suggestions leading to the claimed invention. The question to be

answered is not whether the document used as the starting point suggests the claimed solution but whether the skilled person starting from this document and seeking to solve the objective technical problem would have been led to the invention by the prior art in an obvious way.

2.4.2 Counter-argument 2: No sheath in document D3

The fact that the assembly of document D3 does not have a sheath such as the one in document D5 is irrelevant because claim 8 does not require the presence of a sheath. In any case, the presence of a separate needle sheath is optional in document D5 (see item 10 on page 2 of document D5).

2.4.3 Counter-argument 3: No teaching regarding safety

The argument according to which the skilled person would not have considered document D5 because it does not refer to safety is based on a formulation of the objective technical problem that the board does not endorse (see point 2.3 above).

2.4.4 Counter-argument 4: No housing in document D5

The fact that the device disclosed in document D5 does not comprise a housing is not decisive because the application of the teaching of document D5 would have led the skilled person to provide colour coding of the housing of document D3.

2.4.5 Counter-argument 5: No deviation from a standard

The fact that the skilled person would have adhered to the teaching of document D5, i.e. that the colour

coding should be applied "to the unit container and/or part of the needle assembly such as the needle hub, or the sheath", does not mean that the skilled person would have refrained from providing a coloured housing if the application of the standard would have led to this consequence, as long as the purpose of document D5 would not have been jeopardised.

2.4.6 Counter-argument 6: Multicoloured moulding

The teaching of document E8 that even single pieces can be injection moulded in several colours is not decisive because the skilled person would have had no reason to consider such techniques instead of the most straightforward approach, i.e. single-colour moulding.

2.4.7 Counter-argument 7: Rebuttal by documents E2 to E4

The board is unable to see how documents E2 to E4 "rebut the presumption" that it would have been obvious for a person skilled in the art to combine documents D3 and D5. These documents constitute evidence that colour coding indicating the needle gauge similar to that of the invention was provided on the packaging. The only conclusion that can possibly be drawn from this evidence is that the skilled person would not necessarily have combined documents D3 and D5. Incidentally, documents E2 to E4 appear to teach providing colour coding not only on the packaging but also on the needle hubs.

These documents constitute evidence that colour coding of the gauge of the needle for a needle protection device similar to that of the invention was provided on the packaging.

The argument based on document D2 fails for analogous reasons.

2.4.8 Counter-argument 8: Branding by colour

The fact that the unitary colour of the housing and base of the devices in a product line was used to brand the devices in document E3 does not mean that the skilled person would have refrained from using colours for needle gauge identification according to existing standards. The fact that branding requirements were favoured in a particular case does not mean that this was a necessary course of action.

2.4.9 Counter-argument 9: Hindsight

The fact that nobody actually put the invention into practice does not constitute proof that it was not obvious to combine the teaching of documents D3 and D5. The thorough application of the problem-solution approach leads to the conclusion that the subject-matter of claim 8 lacks inventive step. The board is unable to confirm that the approach used to establish this conclusion was tainted by hindsight.

2.5 Conclusion regarding the patent as granted (main request)

The subject-matter of granted claim 8 lacks inventive step in view of a combination of documents D3 and D5. Consequently, the ground for opposition pursuant to Articles 100(a) and 56 EPC prejudices the maintenance of the patent as granted. Therefore, the appellant's main request cannot be allowed.

3. Auxiliary request I: inventive step of the subject-matter of claim 8 in view of a combination of documents D19 and D5 (Article 56 EPC)

3.1 Admission of document D19 by the opposition division

The appellant objected to the decision of the opposition division to admit document D19 into the proceedings. The appellant argued that this document was not *prima facie* relevant because investigative effort would be required to assess the patentability of the contested claims on the basis of this document.

The board cannot see any legal basis for disregarding a document that was admitted into the proceedings by the opposition division because of its *prima facie* relevance and on the basis of which one of the auxiliary requests was found unallowable (see e.g. the decisions T 2049/16, point 3.2 of the Reasons, and T 617/16, point 1.1.1 of the Reasons). Moreover, the board finds no fault in the way the opposition division acted. The opposition division exercised its discretion based on the correct criterion (*prima facie* relevance) and in a reasonable way. Moreover, the actions of the opposition division were in line with the procedure set out in E-VI, 2.2 (b) of the then applicable Guidelines for Examination (version of November 2017).

Therefore, the board cannot disregard document D19. It will examine whether the opposition division's conclusion regarding the inventive step of the subject-matter of claim 8 of auxiliary request I starting from document D19 is correct.

3.2 Interpretation of claim 8

Claim 8 of auxiliary request I comprises features 8.9 and 8.10. Feature 8.9 corresponds to a condition that has to be fulfilled: "when the needle sheath ... is fitted to the needle hub ... at [the] base", which corresponds to the alternative described in feature 8.5a, according to which the "needle [extends] from a needle hub ... of [the] base". Feature 8.10 expresses another condition that has to be fulfilled: "when [the] needle sheath ... is fitted to the needle hub ... at [the] syringe". This is related to the alternative of feature 8.5b, which refers to a "needle extending ... from a needle hub ... at a syringe ... to which [the] base is fitted". Thus, features 8.9 and 8.10 are understood such that they further define alternatives 8.5a and 8.5b respectively.

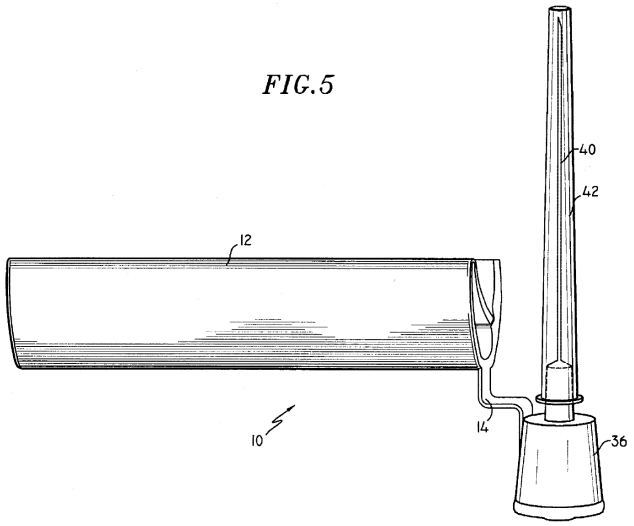
3.3 Examination of inventive step

The opposition division concluded that the subject-matter of claims 1 and 8 of auxiliary request I lacks inventive step in view of the combination of document D19 with document D4 or D5.

3.3.1 Disclosure of document D19

Document D19 discloses a sheath device for a surgical needle 40. The device comprises an assembly 10 having a base 36 and a needle protection housing 12 pivotable relative to the base 36 formed from a moulding material. The needle 40 extends from a needle hub of the base 36 (see Fig. 5). A needle sheath 42 is fitted to the needle hub to cover the needle 40 to prevent its contamination before use.

FIG.5



The needle sheath 42 is fitted to the needle hub at the base 36 to cover the needle 40. There is but a small portion of the needle hub at the base that can be seen by a user (see Fig. 5). The needle 40 is adapted to be covered by the housing 12 after the removal of the sheath 42 when the housing 12 is pivoted to a position in alignment along the longitudinal axis of the base.

3.3.2 Differences

As correctly stated by the respondent, the subject-matter of claim 8 differs from the disclosure of document D19 by features 8.4a, 8.4b and 8.7.

3.3.3 Objective technical problem and obviousness

Since the differences between the subject-matter of claim 8 of auxiliary request I and the disclosure of document D19 are the same as the differences between the subject-matter of granted claim 8 (main request) and the disclosure of document D3, the findings concerning the objective technical problem solved and the lack of inventive step of the subject-matter of

granted claim 8 are directly applicable to claim 8 of auxiliary request I for the same reasons that led to the board's conclusion that the subject-matter of granted claim 8 does not involve an inventive step (see point 2. above).

The appellant's core argument against this finding was that in order to obtain a device encompassed by the claimed subject-matter, the skilled person would have had to make three choices for which there was no incentive, namely:

(1) establish an attachment between housing 12, hinge 14 and base 36 via one-piece injection moulding,
(2) apply the teaching of document D5, and
(3) colour the housing 12 rather than the sheath 42.

The appellant argued that the skilled person could not be expected to take all these steps in the absence of any incentive to do so and that the opposition division's conclusion to the contrary was based on hindsight.

The board cannot endorse this argument for the following reasons:

First, document D19 clearly teaches that the housing 12, the hinge 14 and the base 36 are attached to each other by one-piece injection moulding. The relevant teaching is found in col. 7, lines 5 to 10:

> "*In FIG. 5 housing 12 is attached to hinge 14 which, in turn, is attached at the opposite end thereof away from housing 12 to needle base 36. In this embodiment, as in the embodiment of FIG. 4,*

> *housing 12 and needle base 36 are in an open orientation during molding*" (underlining added by the board).

There would not be any good reason to have housing 12 and base 36 in a special orientation during moulding if they were not to be one-piece injection moulded. Thus, the first step identified by the appellant is already implicit in document D19.

The argument that the word "attached" must be understood in a more general sense and that document D19 defines the word in a way including friction fit, adhesive attachment and ultrasonic attachment but not one-piece injection moulding is based on col. 7, lines 10 to 13. This passage reads as follows:

> "*Needle 40 may thereafter be affixed to base 36 in any suitable manner, such as friction fit, adhesive attachment, ultrasonic welding or a combination thereof*."

However, it is clear that this disclosure is not intended as a definition of the term "attached" (which is not even used) and concerns only the way in which the needle is "affixed" to the base. Therefore, the argument based on this passage is unpersuasive.

In regard to steps 2 and 3 identified by the appellant, the board refers to its conclusion in respect of the inventive step of granted claim 8, i.e. that the skilled person would have considered document D5 and that the application of this teaching would have led the skilled person to obtain a coloured housing.

In view of the above, the subject-matter of claim 8 of auxiliary request I does not involve an inventive step over the disclosure of documents D19 and D5 in combination.

It follows that auxiliary request I cannot be allowed.

4. Auxiliary request II: admittance

Claim 8 of auxiliary request II differs from claim 8 of auxiliary request I in that the needle sheath, instead of being "fitted to the needle hub", is "mated to the needle hub ... by frictional contact with fins ... that extend along the length of the needle hub".

The opposition division decided not to admit auxiliary request II "... *since it introduces a feature that was not part of the granted claims and that is diverging from the invention. See also Guidelines E-VI.2.2*" (point 23.3 of the decision under appeal).

Auxiliary request II was again filed with the statement of grounds of appeal.

In the case at hand, the statement of grounds of appeal was filed before the revised version of the Rules of Procedure of the Boards of Appeal (RPBA 2020) entered into force, i.e. 1 January 2020 (see Article 24(1) RPBA 2020). Thus, pursuant to Article 25(2) RPBA 2020, Article 12(4) to (6) RPBA 2020 does not apply. Instead, Article 12(4) RPBA 2007 continues to apply.

According to Article 12(4) RPBA 2007, the board of appeal has the discretionary power to hold inadmissible facts, evidence and requests which were not admitted in

the proceedings before the department of first instance.

Having considered the circumstances of the case, the board has reached the conclusion that the filing of auxiliary request II constitutes a timely *bona fide* reaction to the admission of document D19 by the opposition division. Document D19 was filed two weeks before the oral proceedings and admitted by the opposition division during the oral proceedings. The then applicable Guidelines (i.e. the version dated November 2017) comprise item E-VI, 2.2 (a), which reads:

> "*The division should admit new facts and evidence only if they are prima facie relevant. Furthermore, if new facts and evidence are admitted under Art. 114(1) because they are prima facie relevant, a request of the proprietor for corresponding amendment would have to be admitted even if submitted after the above final date, because the subject of the proceedings has changed*" (underlining added by the board).

The board understands a "corresponding amendment" to be an amendment triggered by the admission of new facts and evidence. It is undisputed that the amendment on which auxiliary request II is based adds a further feature distinguishing the subject-matter of claim 1 from the disclosure of document D19.

When applying item E-VI, 2.2 (a) of the applicable Guidelines, as interpreted by the board, the opposition division should have admitted auxiliary request II into the proceedings. The Guidelines do not add further conditions such as convergence.

In view of the above, the board, exercising its own discretion under Article 12(4) RPBA 2007, has decided to admit auxiliary request II into the appeal proceedings. As the board exercises its own discretion, there is no need for the board to take a decision on the discretionary decision of the opposition division and the appellant's allegation that a procedural violation under Article 113(1) EPC had occurred in the proceedings before the department of first instance. Moreover, a decision is not necessary because the appellant did not request a reimbursement of the appeal fee.

5. Remittal to the opposition division

Auxiliary request II proposes significant amendments to the independent claims which the opposition division did not assess in substance. Having considered the particular circumstances of the case and the written submissions of both parties regarding auxiliary request II, the board concluded that there are special reasons within the meaning of Article 11 RPBA 2020 for remitting the case to the opposition division and thereby following a corresponding suggestion of the respondent.

Therefore, it is appropriate to remit the case to the opposition division for further prosecution under Article 111(1), second sentence, EPC and Article 11 RPBA 2020.

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:

N. Schneider P. Lanz

Decision electronically authenticated