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Datasheet for the decision of 27 November 2024

Case Number: T 0858/22 - 3.2.01

Application Number: 14735331.2

Publication Number: 2941289

IPC: A61M5/32, A61M25/06

Language of the proceedings: EN

Title of invention:
SPRING CLIP NEEDLE GUARD

Patent Proprietor:
Greiner Bio-One GmbH

Opponent:
B. Braun Melsungen AG

Headword:

Relevant legal provisions:
EPC Art. 100(c), 123(2), 56
RPBA 2020 Art. 12(2), 12(4), 12(6)

Keyword:

Grounds for opposition - added subject-matter (yes)
Amendments - intermediate generalisation
Inventive step - auxiliary request (yes)
Amendment to case - exercise of discretion
Late-filed request - circumstances of appeal case justify admittance (yes) - admitted (yes)

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

Boards of Appeal

Chambres de recours

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Case Number: T 0858/22 - 3.2.01

D E C I S I O N
of Technical Board of Appeal 3.2.01
of 27 November 2024

Appellant: (Patent Proprietor)	Greiner Bio-One GmbH Bad Haller Straße 32 4550 Kremsmünster (AT)
Representative:	Burger, Hannes Anwälte Burger & Partner Rechtsanwalt GmbH Rosenauerweg 16 4580 Windischgarsten (AT)
Appellant: (Opponent)	B. Braun Melsungen AG Carl-Braun-Str.1 34212 Melsungen (DE)
Representative:	Winter, Brandl - Partnerschaft mbB Alois-Steinecker-Straße 22 85354 Freising (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 31 January 2022 concerning maintenance of the European Patent No. 2941289 in amended form.**

Composition of the Board:

Chairman	G. Pricolo
Members:	M. Geisenhofer
	P. Guntz

Summary of Facts and Submissions

I. The appeals were filed by the appellant-patent proprietor and the appellant-opponent against the interlocutory decision of the opposition division finding that, on the basis of the auxiliary request 0A, the patent in suit met the requirements of the EPC.

II. The opposition division held that auxiliary request 0A was inventive over a combination of document

D1 EP 1 180 381 A1

with either the common general knowledge or one of documents

D2 US 2009/0182280 A1 or
D5 WO 2011/129753 A9.

The patent was hence maintained on the basis of auxiliary request 0A.

With regard to the main request (patent as granted) the opposition division decided that it was amended such that it extended beyond what was disclosed in the originally filed application documents, contrary to Article 100(c) EPC.

The main request was the only request in opposition proceedings that was higher-ranked than auxiliary request 0A.

III. Oral proceedings were held before the Board.

(a) The appellant-patent proprietor requested that the decision under appeal be set aside and the patent be maintained as granted (main request) or, in the alternative, that the patent be maintained in amended form according to auxiliary request 3A filed with the patent proprietor's statement of grounds of appeal.

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

IV. Claim 1 of the main request reads as follows:

"*A catheter instrument (1000) comprising a spring clip needle tip shielding device (100), a catheter unit (200), and a needle unit (300);*
wherein said catheter unit (200) comprises a catheter hub (201) and a catheter (202) extending distally from the catheter hub (201), said catheter (202) having a lumen (203) being in flow communication with an interior cavity (204) of the catheter hub (201);
wherein said needle unit (300) comprises a needle hub (301) and a needle (302) with a needle shaft (303) and a needle tip (304) extending distally from the needle hub (301);
said needle hub (301) being connected to the proximal end of the catheter hub (201) and said needle shaft (303) being arranged in the lumen (203) of the catheter (202), in a ready position of said catheter instrument (1000);
said spring clip needle tip shielding device (100) comprising: a base plate (101) with a hole (102) extending there through; at least one resilient arm (103) extending at an attachment point (104) at said base plate (101); wherein said at least one resilient

arm (103) has a resting state, from which it may be urged to yield free passage through said hole (102) in an axial direction of said base plate (101) in a tension state, said at least one resilient arm (103) being adapted for clamping the needle tip (304) of the needle (301) extending through said hole (102) when said resilient arm (103) is in said resting state; and wherein any straight imaginary line extending longitudinally through said hole (102) in the axial direction of said base plate (101) coincides with said at least one resilient arm (103) when said resilient arm (103) is in said resting state; and wherein said spring clip needle tip shielding device (100) is of a rigid material, and at least a part thereof, in use coming in contact with walls of the interior cavity (204) of the catheter hub (201), is coated with a solid lubricant (106); and
said spring clip needle tip shielding device (100) being arranged inside the interior cavity (204) of the catheter hub (201), and said needle being arranged through said hole (102) with the resilient arm (103) being urged into its tension state by said needle shaft (303)."

Claim 1 of the auxiliary request 3A further recites the feature: "*wherein the catheter (202) and the catheter hub (201) are made of a polymeric material*" (following the feature "*said catheter (202) having a lumen (203) being in flow communication with an interior cavity (204) of the catheter hub (201)*").

Compared to claim 1 of auxiliary request 3A, claim 1 of auxiliary request 0A further recites the feature: "*wherein the rigid material is metal*".

V. The arguments of the appellant-patent proprietor which were relevant for the present decision can be summarized as follows:

(a) The subject-matter claimed in the main request (patent as granted) was disclosed in the application as originally filed.

(b) Auxiliary request 3A was filed during opposition proceedings and maintained. The opposition division's decision on the main request implicitly encompassed this request such that it was part of the appealed decision and consequently also of the appeal proceedings.

(c) At least, auxiliary request 3A should be admitted since its examination did not require additional issues to be discussed over the main request and auxiliary request 0A.

(d) The subject-matter of claim 1 of auxiliary request 3A was disclosed in the application as originally filed and involved an inventive step.

VI. The arguments of the appellant-opponent which were relevant for the present decision can be summarized as follows:

(a) The main request was amended such that it extended beyond what was disclosed in the application as originally filed.

(b) Auxiliary request 3A was filed late as it was filed after expiry of the time limit set by the opposition division according to Rule 116(2) EPC.

(c) The order of requests was amended during oral proceedings before the opposition division such that the opposition division's decision did not encompass auxiliary request 3A. It should have been filed as a request preceding the maintained auxiliary request 0A.

(d) Even if admitted, auxiliary request 3A did not remedy the unallowable amendment of the main request but still lacked disclosure in the originally filed application.

(e) The subject-matter of auxiliary request 3A lacked an inventive step when starting from document D1 as closest prior art. The general knowledge, in the alternative one of documents D2 or D5 rendered the subject-matter of auxiliary request 0A obvious.

Reasons for the Decision

Main request

Amendments (Article 100(b) EPC)

1. The subject-matter of claim 1 of the main request lacks disclosure in the application as originally filed.

1.1 The opposition division held that claim 1 of the main request introduced added subject-matter. They concluded that the inclusion of the feature

"*and at least a part thereof, in use coming in contact with walls of the interior cavity (204) of the catheter hub (201), is coated with a solid lubricant (106)*"

constituted an unallowable generalisation of what was disclosed on page 6, lines 21-24. In their view, the omission of the information that the spring clip needle tip shielding device was made of metal whereas the catheter hub was made of a polymer was unallowable (reasons 15.6).

1.2 The appellant-patent proprietor disagreed and argued that on page 6, the material of the spring clip needle tip shielding device was specified to be a rigid material that was only preferably metal ("*in a rigid material ... for example a metal, such as stainless steel*").

Furthermore, the material of the catheter hub needed not necessarily be a polymeric material since the skilled person knew from his expert knowledge various alternative materials that were suitable to produce the catheter and the catheter hub.

1.3 The Board considers that the omission of the feature that the catheter hub is made of a polymeric material results in an unallowable intermediate generalization.

1.3.1 Originally filed claim 1 refers to a spring clip needle tip shielding device that is made of a rigid material, and at least a part thereof is coated with a solid lubricant. However, originally filed claim 1 does not specify which parts of the spring clip needle tip shielding device shall be coated with the lubricant.

1.3.2 This information which was later introduced into the claim has been taken from the description. In fact, the originally filed application provides on page 2, lines 12 to 28 and page 6, second paragraph, the information on where to apply the lubricant. In this context, the

application as filed distinguishes between two particular problems solved by the coating:

- avoiding damages of the walls of the interior cavity of the catheter hub by the scraping of the spring clip there against; and
- avoiding unpleasant sounds when the spring clip needle tip shielding device glides on the needle.

Claim 1 of the main request recites that the lubricant is arranged on those parts of the spring clip needle tip shielding device that, in use, come into contact with walls of the interior cavity of the catheter hub. This coating is hence a measure to remedy the first problem identified above, i. e. the problem of damaging the walls of the catheter hub.

1.3.3 The effect of avoiding to damage the interior walls of the catheter hub is, however, inextricably linked to the hub being made of polymeric material. The relevant passage on page 6 *expressis verbis* only discloses a polymeric catheter hub (cf. line 16). No alternative material for the catheter hub apart from a polymer is mentioned.

(a) The appellant-patent proprietor argued that the skilled person knows suitable alternative materials for producing the catheter hub such that the information that the material is a polymeric material can be omitted.

(b) In the Board's view, it is irrelevant whether the skilled person knows from his expert knowledge other suitable materials, but the question is rather whether the material disclosed in the originally filed application can be omitted or is

inextricably linked to the effect of avoiding to damage the catheter hub.

(c) The problem of of damaging the walls of the catheter hub arises when the material of the hub is is softer than the (rigid) material of the spring clip needle tip shielding device. However, not every material suitable for producing the catheter hub is susceptible of being damaged by the spring clip, such that the material of the walls of the catheter hub is inextricably linked to the added feature that at least a part of the spring clip needle tip shielding device, which in use coming in contact with walls of the interior cavity of the catheter hub, is coated with a solid lubricant.

1.3.4 Omitting the information that the catheter hub is made of polymeric material hence is an unallowable intermediate generalization of what is disclosed in the originally field application.

Auxiliary request 3A

Admissiblility (Articles 12(4) and (6) RPBA)

2. The Board admitted auxiliary request 3A.

2.1 The appellant-opponent requested to not admit this request.

2.2 During opposition proceedings auxiliary requests were filed by the patent proprietor. Among these, auxiliary request 3A was filed shortly before the oral proceedings.

During the oral proceedings, after discussion of the main request, the opposition division informed the parties that they could only acknowledge disclosure in the originally filed application for the specific material combination of the spring clip needle tip shielding device being made of metal and the catheter hub being made of a polymer (see minutes of oral proceedings, point 14; see also decision, point 15.6 of the reasons). The opposition division also stated that none of the auxiliary requests on file complied with Article 123(2) EPC for the same reasons (minutes, point 14).

In reaction thereto , the appellant-patent proprietor filed a new auxiliary request 0A as the highest ranking auxiliary request (point 19 of the minutes). The other auxiliary requests, including auxiliary request 3A, were however not abandoned: the patent proprietor only stated that they did not wish to discuss the other auxiliary requests on file (point 17 of the minutes).

2.3 In appeal proceedings the patent proprietor has however re-ordered the auxiliary requests by ranking auxiliary request 3A higher than auxiliary request 0A. This constitutes an amendment of the appeal case which is only to be admitted at the discretion of the Board according to the principles laid down in Article 12(2), (4) and (6) RPBA.

2.3.1 In the present case, the appellant-patent proprietor when changing the order of the auxiliary requests during opposition proceedings did not prevent the opposition division from taking a decision on the decisive issues regarding auxiliary request 3A. To the contrary, it was clear from the discussion, and was stated in the minutes, that the opposition division

held auxiliary request 3A not to comply with Article 123(2) EPC for the same reasons as set out under Article 100(c) EPC with regard to the main request.

The Board hence considers the present re-ordering of auxiliary requests 0A and 3A not to be the typical case of forum shopping by avoiding a decision of the department of first instance and trying to get a direct decision of the Board of Appeal which was envisaged by the second sentence of Article 12(6) RPBA.

2.3.2 Auxiliary request 3A differs from the main request only in that the catheter hub's material is specified to be a polymeric material. This amendment is not complex and does not require a discussion on new objections. The relevant passages of the application as originally filed still are the same as with regard to the main request (page 6 of the description and claim 1) such that discussing this request does not require a significant additional effort which would be detrimental to procedural economy.

Furthermore, the amendments to auxiliary request 3A appeared at first sight to remedy the objection of unallowable amendment with regard to the main request as set out above.

2.3.3 In this context, it is irrelevant whether auxiliary request 3A was filed in opposition proceedings before or after expiry of the time limit set under Rule 116(2) EPC. For a decision whether a request can be admitted in appeal proceedings, the criteria to be used are defined in Article 12(4) RPBA. According to these criteria and in view of the above considerations, the Board exercised its discretion to admit auxiliary request 3A into the appeal proceedings.

Amendments (Article 123(2) EPC)

3. The subject-matter of independent claim 1 of auxiliary request 3A is disclosed in the application as originally filed.

3.1 The appellant-opponent argued that the application only provided support for a spring clip needle tip shielding device being made of metal as the opposition division held with regard to the main request (reasons 15.6). Generalizing the material of the spring clip needle tip shielding device to be a rigid material instead of metal was hence an unallowable intermediate generalization.

3.1.1 The Board does not share this view. Originally filed independent claim 1 was not restricted to a spring clip needle tip shielding device made of metal but referred to a spring clip needle tip shielding device being made of a rigid material. Since the claim further defines a coating of at least a part of the spring clip needle tip shielding device with a solid lubricant, the only information added to claim 1 is hence which parts of the spring clip needle tip shielding device are coated with the lubricant.

3.1.2 The specification of the coated parts can be derived as set out above with regard to the main request from the passage on page 6, lines 11 - 24 of the originally filed description whereby the information on the lubricant's location is not inextricably linked to metal spring clip needle tip shielding devices.

(a) The first sentence of the relevant passage on page 6 reads as follows:

"*The spring clip needle tip shielding device 100 is manufactured in a rigid material, with good flexibility. Such a material is for example a metal, such as stainless steel.*"

Metal is hence presented as an example for the rigid material used for producing the spring clip needle tip shielding device.

The effect of damaging the walls of the catheter hub is not presented as arising only with metal either, but generally with a rigid material scraping against the polymeric material of the hub's walls, as set out in line 14 - 16 of page 6:

"*The rigid material of the spring clip needle tip shielding device 100, such as metal, such as stainless steel, risk to damage the walls...*"

Again, metal is just an example.

(b) The appellant-opponent argued that lines 21 - 24 on page 6 referred to "*problems associated with metal spring clip needle tip shielding devices*" (underlining added by the Board).

(c) It is, however, clear from the above-cited passages on the same page that the problem of damaging the walls of the hub is not necessarily associated with spring clip needle tip shielding devices made of metal but might generally occur with rigid materials.

3.1.3 The Board hence sees not reason why claim 1 should be restricted to a spring clip needle tip shielding device being made of metal.

3.2 The appellant-opponent further argued that added subject-matter also resulted from the fact that claim 1 of auxiliary request 3A required the spring clip needle tip shielding device to be coated on those parts that, *in use*, were coming in contact with walls of the catheter hub. Page 6 of the originally filed application however referred to contact surfaces during production of the cathether ("*during arrangement*"), hence a state not "*in use*" but "*before use*".

3.2.1 The relevant passage of claim 1 reads as follows:

"...*and wherein said spring clip needle tip shielding device is of a rigid material, and at least a part thereof, in use coming in contact with walls of the interior cavity (204) of the catheter hub (201), is coated...*".

3.2.2 In the Board's understanding of claim 1, the term "*in use*" refers in the expression "*the part, in use coming in contact*" to the use of the spring clip needle tip shielding device, not to the catheter as such. This device is in use as soon as is brought into its destined position within the catheter. Thus, the use of this device is not restricted to the situation where the produced catheter with inserted needle and spring clip needle tip shielding device is later inserted into a patient's vene but encompasses any situation where the device is already placed on the needle. Therefore, when the needle with attached spring clip needle tip shielding device is inserted into the catheter hub during production, the latter device is already being used. The surfaces coated with the lubricant hence include not only the surface coming into contact with the spring clip needle tip shielding device during the later use of the catheter but also those surfaces

having contact during use of the needle tip shielding device in the production of the catheter.

3.2.3 The appellant-opponent referred to a plurality of passages in the application as filed containing the word "use".

However, all of these passages refer to the use of the catheter (and not to the use of the spring clip needle tip shielding device). Thus, these passages do not contribute with relevant information.

3.3 The appellant-patent proprietor requested to not admit this line of argument since it was only raised at appeal stage.

This can be left undecided since the argument as set out above anyway does not convince in substance.

Inventive step (Article 56 EPC)

4. The subject-matter of claim 1 of auxiliary request 3A is not rendered obvious by the prior art.

4.1 The opposition division held that the subject-matter of claim 1 of auxiliary request 0A is inventive (reasons 16.2). The reasoning provided by the opposition division also applies *mutatis mutandis* to auxiliary request 3A.

4.2 It is undisputed that document D1 represents the closest prior art. The subject-matter of claim 1 differs therefrom only in that at least a part of the spring clip needle tip shielding device, in use coming

in contact with walls of the interior cavity, is coated with a solid lubricant.

The lubricant serves to minimise the risk that the scraping of the spring clip against the walls of the catheter hub releases chips from the hub that may be introduced into the blood vessels of the patient (see paragraph [0005] of the published patent). This is also undisputed by the parties.

4.3 The appellant-opponent argued that using a solid lubricant for coating the spring clip needle tip shielding device is rendered obvious by the common general knowledge of the skilled person.

4.3.1 The Board disagrees since the problem of releasing chips from the catheter hub's surface is not an issue in Dl. The skilled person hence had no incentive to reduce friction between the spring clip needle tip shielding device and the catheter hub. Without any hint that friction between spring clip needle tip shielding device and catheter hub needs to be reduced, the skilled person would not consider coating the parts of the spring clip needle tip shielding device coming into contact with the catheter hub with a solid lubricant.

(a) The appellant-opponent argued that the patent in suit itself confirmed in paragraph [0005] that the skilled person was aware of the problem and hence had an incentive to avoid this problem with the catheter of D1.

(b) The Board considers the insight described in the patent in suit in paragraph [0005] with regard to known metal spring clip needle tip shielding devices as a part of the invention according to the

patent in suit. Paragraph [0005] does not describe the general knowledge but refers to the problems that were recognized and then solved by the claimed coating. But even if scraping as such would have been known as a general problem, the concept of avoiding this scraping by reducing friction between the spring clip needle tip shielding device and the catheter hub was still not known.

(c) In the absence of any evidence that the skilled person indeed knew both the problem of scraping and the concept of reducing friction to avoid the undesired scraping effect from his expert knowledge before the priority date of the patent in suit, the Board cannot acknowledge that the skilled person indeed had an incentive to strive for a solution avoiding the problem of scraping.

4.4 The appellant-opponent further argued that using a solid lubricant is rendered obvious by D2.

4.4.1 The appellant-opponent argued that D2 renders it obvious to reduce friction by adding a coating whereby the skilled person would cover the entire spring clip needle tip shielding device, hence including also the parts that in use come in contact with the catheter hub.

4.4.2 In the Board's understanding, D2 teaches in paragraph [0035] to use a lubricant between needle and V-clip (58). This coating shall be applied only to the first arm (62) of the V-clip (58) as set out in several passages of paragraph [0035]:

"*...added to the metal surface of the first arm 62.*"; and

"*...lubricant may be placed on the surface of either the needle 30 and/or the face of the first arm 62.*"

4.4.3 If the skilled person applied the teaching of D2 to D1, they would not arrive at the subject-matter of claim 1 since claim 1 requires a lubricant between spring clip needle tip shielding device and catheter hub (not the needle). The skilled person when applying the teaching of D2 would only use a lubricant at the parts of the spring clip needle tip shielding device coming into contact with the needle, i. e. at the ends (132) of arms (122) and around the hole in the base plate (126)), but not at the parts of the spring clip needle tip shielding device coming into contact with the interior of the catheter hub such that the resulting device would not fall under claim 1.

(a) The appellant-opponent argued that the spring clip needle tip shielding device known from D1 was so small that the skilled person would not consider coating only a part thereof but would have coated the entire spring clip needle tip shielding device. Coating only a part of the spring clip needle tip shielding device was almost impossible.

(b) The Board notes that the V-clip of D2 has a size similar to the spring clip needle tip shielding device of D1. If the skilled person is able to coat only a part of the V-clip of D2, it is not understandable why they should not be able to also coat only part of the spring clip needle tip shielding device known from D1. In the absence of any evidence, the appellant-opponent's argument that the skilled person would only consider coating the entire spring clip needle tip shielding device

has to be regarded as an unsubstantiated allegation.

(c) Moreover, in the absence of any hints in D2 that coating the entire spring clip needle tip shielding device might be useful and/or would result in any advantages, there is no apparent reason why the skilled person would consider coating the entire spring clip needle tip shielding device of D1. This would rather be considered as an unnecessary waste of solid lubricant which should be avoided.

4.5 The appellant-opponent finally argued that using a solid lubricant was also rendered obvious by D5.

4.5.1 With their grounds of appeal, the appellant-opponent argued that D5 rendered it obvious to use a polymeric material for reducing friction between spring clip needle tip shielding device and catheter hub.

4.5.2 D5 indeed discloses the concept of reducing the friction between spring clip needle tip shielding device (100) and catheter hub (200) by using a plastic or polymeric needle tip shielding device (cf. page 21, lines 28 - 35). This is, however, not a metal spring clip needle tip shielding device coated with a solid lubricant as required by claim 1. Taking this teaching into account, the skilled person would replace the metallic spring clip needle tip shielding device by a spring clip needle tip shielding device made of polymeric material, hence not arriving at a device according to claim 1.

4.5.3 During oral proceedings before the Board, the appellant-opponent further argued that it was obvious from D5 (cf. page 19, lines 26 - 33) to polish those

surfaces of the spring clip needle tip shielding device coming into contact with the catheter hub. Polishing implied use of a polish whereby a small amount of this polish would remain on the spring clip needle tip shielding device, hence providing a coating that reduced friction.

4.5.4 The Board notes that D5 does not disclose use of a polish for polishing.

Polishing does not necessarily require a polish but can be carried out using a rough surface of a polishing block or cloth. Use of a polish is hence not disclosed implicitly in D5 either.

4.5.5 Even if the skilled person would use a polish in D5, this polish cannot be considered as a substance that builds up to form a layer of solid lubricant after polishing. A lubricant serves to reduce friction whereas a polish serves to grind a surface, i. e. if a liquid polish is used, the polish contains an amount of solid particles that grind the treated surface when being moved over it. A remaining amount of dried polish hence would still contain these solid particles such that such a layer, if any layer is formed, would increase friction but not reduce it. A layer of remaining polish hence cannot be considered as a coating of solid lubricant.

4.6 The Board therefore considers the subject-matter of claim 1 of auxiliary request 3A to imply an inventive step.

5. The adaptation of the description was not objected by the appellant-opponent.

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 with the order to maintain the patent in amended form on the basis of the following documents:

   - Claims 1-7 according to auxiliary request 3A as filed with the letter dated 17 October 2022;
   - Description paragraphs 1-6 and 8-23 as granted and paragraph 7 according to auxiliary request 3A as filed with the letter dated 17 October 2022;
   - Figures 1 and 2 as granted.

The Registrar: The Chairman:

H. Jenney G. Pricolo

Decision electronically authenticated