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Datasheet for the decision of 21 January 2016

Case Number: T 2237/14 - 3.2.02

Application Number: 10009582.7

Publication Number: 2319556

IPC: A61M5/32, A61M25/06, A61B5/154, A61B5/15

Language of the proceedings: EN

Title of invention:
Needle tip guard for hypodermic needles

Patent Proprietor:
B. Braun Melsungen AG

Opponents:
Becton Dickinson GmbH
Becton Dickinson Austria GmbH (intervener)

Headword:

Relevant legal provisions:
EPC Art. 54, 56, 100(a), 100(c)
RPBA Art. 13(1), 13(3)

Keyword:
Late-filed argument - admitted (no)
Added subject-matter (no)
Fresh ground for opposition - admitted (yes)
Remittal (no)
Prior use - admitted (yes)
Prior use - admitted (no)
Novelty - (yes)
Inventive step - (yes)

Decisions cited:
G 0001/94, G 0003/04, T 0389/86, T 0782/92

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

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Case Number: T 2237/14 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 21 January 2016

Appellant: (Opponent 1)	Becton Dickinson GmbH Tullastrasse 8-12 69126 Heidelberg (DE)
Representative:	Herr, Jochen Baker & McKenzie Theatinerstraße 23 80333 München (DE)
Respondent: (Patent Proprietor)	B. Braun Melsungen AG Carl-Braun-Strasse 1 34212 Melsungen (DE)
Representative:	Kinkeldey, Daniela Bird & Bird LLP Maximiliansplatz 22 80333 München (DE)
Party as of right: (Intervener - Opponent 2)	Becton Dickinson Austria GmbH Millennium Tower Handelskai 94-96 1200 Wien (AT)
Representative:	Weiser, Andreas Patentanwalt Kopfgasse 7 1130 Wien (AT)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 9 December 2014 rejecting the opposition filed against European patent No. 2319556 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 to reject the opposition, which was announced at the oral proceedings held on 21 November 2014 and posted on 9 December 2014.

The notice of appeal was filed (by fax) on 2 December 2014 and the appeal fee paid on the same day. The statement setting out the grounds of appeal was received on 15 April 2015. The appellant-opponent requested acceleration of the proceedings.

II. In the opposition proceedings, the appellant-opponent had raised for the first time a late-filed objection under Article 100(c) EPC. The Opposition Division considered the line of argument prima facie not relevant, as explained under point 2 of the reasons for the decision, and consequently did not admit the ground for opposition pursuant to Article 100(c) EPC into the proceedings.

III. With letter dated 24 February 2015, Oberlandesgericht Düsseldorf 2. Zivilsenat filed a request for acceleration pursuant to a notice from the EPO (OJ EPO 2008, 220).

IV. An intervener filed a notice of intervention on 30 March 2015 and paid the opposition fee on the same day.

The intervener requested acceleration of the proceedings.

In its notice of intervention (pages 4 and 5), the intervener said it wished to adopt the argumentation of the appellant-opponent relating to the objection under

the ground for opposition pursuant to Article 100(c) EPC.

Page 2 of the notice of intervention, under the heading "Adoption of arguments of opponent I by opponent II", contains the following:

"*To avoid repetitions and a reproduction of all materials currently on file, opponent II herewith adopts all arguments of opponent I by reference to all past submissions of opponent I.*

In particular, opponent II relies on all documents D1 – D18 filed with the notice of opposition of opponent I. Since documents D1 – D18 are all part of the official file, they need not be re-submitted here in their entirety.

In addition, opponent II herewith re-submits the late filed documents:
... E11.1-5 public prior use "Guardian Design" as own submissions of opponent II. As to the relevance of these documents, reference is made to the respective submissions of opponent I."

V. With letter of 11 September 2015, the appellant-opponent filed evidence of alleged prior uses.

VI. Oral proceedings were held on 20 and 21 January 2016.

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

The respondent-patent proprietor requested that the appeal be dismissed or, in the alternative, that the decision under appeal be set aside and that the patent

be maintained on the basis of one of the auxiliary requests I to XI filed with letter date 6 August 2015 (same as in first instance proceedings) and auxiliary requests XII to XIX filed with letter dated 14 August 2015.

The intervener requested that the decision under appeal be set aside and that the patent be revoked.

The request for remittal submitted by the respondent-patent proprietor in the written proceedings was withdrawn during the oral proceedings.

VII. The following documents are cited in the decision:

P3: US 60/031399: third priority document of the patent in suit filed 19 November 1996.

D1: EP-A-0747085
D2: EP-A-0747083
D3: US-A-5215525
D4: US-A-4978344
D16: WO-A-96/22800

Exhibit 12.1: United States District Court – District of Nevada, Deposition of Mr Kuracina, New York, Tuesday, August 4, 2015,

Exhibit 12.5: Copy of a letter (2 pages) dated November 27, 1996, from Mr John R. Gordon addressed to Rita Vacca, patent attorney, at Sherwood-Davis & Geck.

Exhibit 12.11: Report (one page) by Mr John Gordon dated 18 November 1996 on a meeting at Johnson and Johnson Medical, Inc. on the same date.

Exhibit 12.12: Copies of slides of a presentation given by Mr Kuracina to Johnson and Johnson Medical, Inc. dated March 26, 1997, pages TK0000145 to TK0000183.

VIII. The patent in suit is based on a divisional application of EP05104948.4, which in turn is a divisional application of EP97915856.5 filed on 27 February 1997.

The description and drawings of the second divisional application (basis for the patent in suit), the first divisional application and the parent application are identical. The set of claims is different in each of the applications.

IX. Claim 1 of the patent as granted reads as follows:

"A needle guard assembly comprising:

a) a catheter hub (13);
b) a needle hub (9, 12, 112) with a fixedly attached needle (10) having a sharpened distal end (11);
c) a needle guard (22, 22a, 220) slidably mounted on the needle (10);
d) the needle guard (22, 22a, 220) comprising a movable needle trap (41), the needle trap (41) being biased toward the needle (10);
e) the needle trap (41) of the needle guard (22, 22a, 220) advancing over the sharpened distal end (11) of the needle (10) and thereby entrapping the sharpened distal end (11) as the needle guard (22, 22a, 220) is urged forward near the sharpened distal end (11) of the needle (10);
f) limiting means for limiting the forward movement of the needle guard (22, 22a, 220) along the needle (10);
g) the needle guard assembly further comprising a coupling mechanism preventing a mechanical separation of

the needle guard assembly from the catheter hub (13) until the sharpened distal end (11) is safely contained within the needle trap (41),
wherein the coupling mechanism comprises an arm (45) having a proximal end and a distal end, the proximal end of the arm being attached to the movable needle trap (41),
the distal end of the arm (45) including a projection (42) that is releasably retained with the catheter hub (13),
characterised in that the projection (42) of the distal end of the arm (45) is releasably retained within a recess (32) of the catheter hub (13);
h) and wherein the limiting means comprises a tether (24)."

X. The arguments of the appellant-opponent and the intervener which are relevant for the present decision can be summarised as follows:

Added subject-matter

The subject-matter of claim 1 was an unallowable intermediate generalisation of the embodiments shown in Figures 103 to 105, because essential features of this embodiment were not present in claim 1. Moreover, general paragraphs [0031] and [0036] (of the published version of the application) could not be used as a basis for claim 1 because they referred to different, separate embodiments. In addition, by explicitly indicating that for releasing the catheter hub, the arm had an inward movement following the inward movement of the needle trap, paragraph [0036] unequivocally implied that the recess retaining the projection on the arm had to be an inner recess of the catheter hub, despite the fact that this was the only place in the description of the

application as filed where the adjective "inner" was not explicitly associated with recess. In the rest of the description of the application, each time the word "recess" appeared, it was in the expression "inner channel, recess, slot of undercut 32", which was an additional indication that nothing other than an inner recess had ever been meant in the application as filed.

Admissibility of the prior uses

The two alleged prior uses Sherwood-Davis & Geck, and Johnson and Johnson Medical, Inc. had to be admitted into the appeal proceedings because both of them were evidence for the disclosure of IV catheter assemblies according to Figures 19 and 35 of priority document P3, and these disclosures were more relevant than any of the documents on file. The relevant documents concerning the prior uses had been filed as soon as possible after the American judge had released them.

The "Guardian Design" prior use was mentioned by the intervener at the earliest possible stage, namely when filing its notice of intervention, and the relevant documents were also mentioned therein.

Novelty

In view of the Johnson and Johnson Medical, Inc. prior use

The statement on page 49 of P3 was clear in itself and did not need to be combined with any further documents. Indeed, it mentioned that prototypes according to Figures 19 and 35 had been manufactured, so that there could not be any doubts about the features of these prototypes. Except for the recess, which was said to

have been replaced by a through hole, all the other features had to be present. Eight prototypes were shown to people at Johnson and Johnson Medical, Inc. during a meeting at which the feature of the recess was also discussed, as indicated in the meeting report (exhibit 12.11). Hence, all the features had been subject of discussion.

In view of D1

The embodiment according to Figure 2A anticipated the subject-matter of claim 1. This figure showed two elongated members forming an inside chamber for entrapping the needle tip when it was withdrawn. The distal end of this chamber ended proximally from the distal end of the elongated members, so that two arms were defined between the distal end of the chamber and the distal end of the elongated members. At their distal ends these arms were also provided with projections being retained in an inner recess of the catheter hub. The other features also being present, this embodiment anticipated the subject-matter of claim 1.

In view of D3

The embodiment of Figures 11 and 12 anticipated the subject-matter of claim 1. Each of the elongated members with a saw-tooth-like structure constituted a needle trap with an arm anticipating those of claim 1. This was particularly clear with the elongated member which had the two teeth. In this case the distance from the distal end of the first tooth to the distal end of the second tooth clearly constituted an arm in the sense of claim 1. As this arm was also provided with a protrusion retained in an inner recess and the other features were

also disclosed, this embodiment anticipated the subject-matter of claim 1.

In view of D2

The embodiment shown in this document had a recess on the outer side of the catheter hub. The projection on the arm was retained behind the flange of a Luer lock connection on the catheter hub. No specific definition of the word recess was given in the patent in suit, so that a difference in diameter had also to be considered as defining a recess. The other features also being disclosed, the subject-matter of claim 1 was anticipated by D2 as well.

Inventive step

Admissibility of lines of argument based on D16

Document D16 had already been cited in the notice of intervention, so it was part of the proceedings right from the start. An inventive step objection based on this document was therefore admissible.

Starting from D2

Starting from D2, it was a simple alternative to add a rear wall on the hub behind the hook, or to replace the retaining flange by a retaining recess in the catheter hub. Basically, it was an obvious kinematical inversion, i.e. instead of using the recess 48 for the flange and none for the hook, it was the other way round. The subject-matter was therefore not inventive when considering D2 alone, but would, in any case, not be inventive when considering the teaching of D3 or D1, as these documents taught the use of a recess to retain the

protrusion on the arm. The question of whether the use of the Luer lock connection would be lost or not, was not relevant, because this was an organisational question, not a technical one.

Starting from D3

The provision of an arm or arms at the end of the existing needle trap to hold the protrusion was a trivial amendment, on top of that suggested by Figures 20 and 21 of the same document. Should the objective problem have been to get a greater lever effect to free the protrusion from its retaining recess, then this could not be inventive either, because the lever theory was well known to the person skilled in the art. Even D2 showed an application of the lever theory in that the hook was at a distance from the point of rotation, for exactly the same reason.

Hence, the subject-matter of claim 1 was not inventive.

XI. The arguments of the respondent-patent proprietor which are relevant for the present decision can be summarised as follows:

Added subject-matter

As the Opposition Division recognised in its decision, claim 1 was based on general paragraphs [0031] and [0036], and in the latter the word “recess” was used on its own without any adjective. These paragraphs belonged to the general part of the description and the person skilled in the art would understand that the general teachings of the different paragraphs could be combined, provided this was technically compatible.

Admissibility of the prior uses

The two alleged prior uses, Sherwood-Davis & Geck, and Johnson and Johnson Medical, Inc., had been filed by the appellant-opponent after it had filed the statement setting out the grounds of appeal, and for that reason alone had not to be admitted. The relevant page of priority document P3 had been part of the opposition proceedings from the very start, so that the appellant-opponent had had ample time to consider its relevance. In addition, in both alleged prior uses it was not established what had been shown, and no declaration by any of the persons present had been filed.

The third prior use, "Guardian Design", had not been substantiated at all in the appeal proceedings, so for that reason alone it had to be disregarded.

Novelty

In view of the Johnson and Johnson Medical, Inc. prior use

There were serious doubts about what was manufactured and what was shown at the meeting with the Johnson and Johnson Medical, Inc. people. In his deposition (exhibit 12.1), Mr Kuracina explained that prototypes did not necessarily have all the features of a finished product, and that so many prototypes had been manufactured that he was unable to remember which of them had been shown. Moreover, the report of the meeting did not mention a recess but a ring, which was not necessarily the same thing. It was further noted that there was no deposition on file from any of the persons present at the meeting. Hence, it was not possible to establish what had been shown.

In view of D1

The embodiment of Figure 2A did not show any arm attached to a needle trap as required by the wording of claim 1. No such arm, distinct of the needle trap, could be seen in this figure. The appellant-opponent and the intervener made an artificial division of an element the person skilled in the art could only see as a single one.

In view of D3

Here as well, no arm could be distinguished from a needle trap on Figures 11 and 12. The embodiment of these figures was an embodiment in itself and the person skilled in the art would not recognise any arms. Again the reading of the appellant-opponent and the intervener was outside the objective teaching of the document.

In view of D2

For a person skilled in the art, a difference in diameter behind a flange is not a recess, as was also recognised by the Opposition Division. Therefore, D2 did not anticipate the subject-matter of claim 1 either.

Inventive step

Admissibility of lines of argument based on D16

Up to the oral proceedings, this document was not substantiated in any of the objections presented in the appeal proceedings, and no reasons were presented for the lateness of submission of these lines. Lines of

argument based on that document were therefore not admissible.

Starting from D2

This IV catheter assembly worked with a standard Luer lock connection and a locking or retaining arm with a hook. Why would the person skilled in the art decide to get rid of the connectability? D3 and D1 could not suggest the subject-matter of claim 1 either. They disclosed completely different solutions for protecting the needle tip and retaining/releasing the catheter hub, and there appeared to be no reason why the person skilled in the art might take out one particular feature of these specific constructions and integrate it into the assembly of D2.

Starting from D3

The technical effect of the arms was to give more flexibility for designing the needle guard and trap, because it could be placed outside the catheter hub.

In D3, the needle guard/needle trap assembly filled the whole interior space of the catheter hub, so that there was no space left for adding any arms. D2 disclosed a completely different construction, so that it was not at all clear which – if any - features the person skilled in the art would take out of this embodiment and transfer into the assembly of D3. Figures 20 and 21 of D3 could not help either, because in that embodiment not only was the needle tip not entrapped, but the arms were also released by an operator.

Hence, the subject-matter of claim 1 was inventive.

Reasons for the Decision

1. The appeal is admissible. The filing of the notice of appeal and the payment of the appeal fee between the announcement of the impugned decision at the oral proceedings and its notification by post is not detrimental to the admissibility of the appeal (T 0389/86, OJ EPO 1988, 87).

2. The intervention is admissible.

3. The invention

The invention is about a needle guard assembly for protecting medical staff from needle sticking when using an IV catheter. The needle guard includes a needle trap which is urged against the needle shaft. When withdrawing the needle from the patient's body, the needle slides proximally within the catheter and the needle guard until the needle tip is moved proximally of the needle trap and the latter entraps the needle tip in a safety position in front of the needle tip. At the same time as the needle trap gets into its needle tip protecting position, it frees the catheter hub, so that the protected needle can be taken away from the catheter hub without any risk of injury to medical staff, leaving the IV catheter in the patient's body. The needle guard is kept from falling off the needle by limiting means (tether).

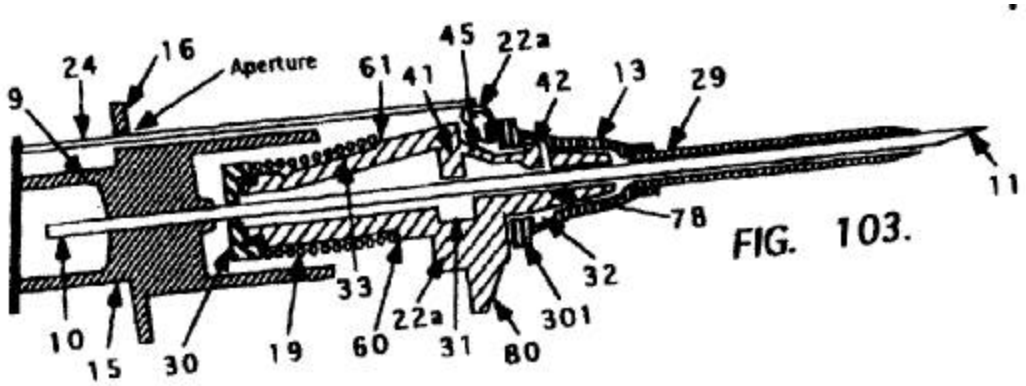


FIG. 103.

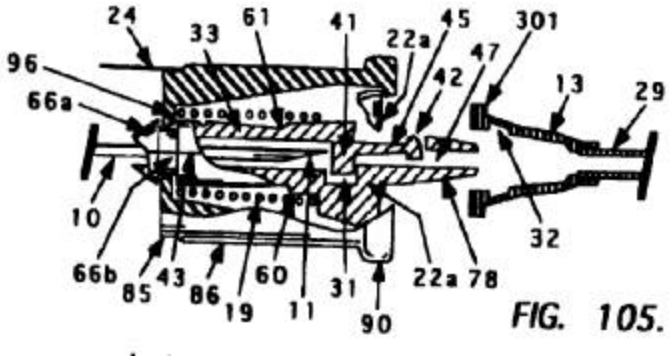


FIG. 105.

4. Fresh ground/remittal

As explained above (point II), in the opposition proceedings, the Opposition Division did not admit the late-filed ground for opposition pursuant to Article 100(c) EPC into the proceedings (point 2 of the reasons).

In its notice of intervention, the intervener stated that it wished to adopt the argumentation of the appellant-opponent relating to that objection under the ground for opposition pursuant to Article 100(c) EPC.

This ground for opposition, having not been admitted into the opposition proceedings, hence constitutes a

fresh ground for opposition as far as the appeal proceedings are concerned.

According to G1/94, the Enlarged Board of Appeal considered that the intervener has a right to base its intervention/opposition on any ground for opposition of Article 100 EPC. It held that, if a fresh ground for opposition is raised by the intervener, the case should be remitted to the first instance for further prosecution, unless special reasons present themselves for doing otherwise, ...(G1/94, point 13 of the reasons).

This reasoning would in principle have obliged the Board to remit the present case. However, the Board considered that special reasons are present for not doing so.

As mentioned above, the Opposition Division made a prima facie analysis of the objection. According to the Board, it would therefore appear to be a rather formal approach to remit the case back to the Opposition Division, only for it to most probably confirm the opinion already expressed in the decision on the basis of that prima facie analysis.

Additionally, in the present proceedings (concerning a patent having a filing date of 27 February 1997), the appellant-opponent, the intervener and the Judge at the court in Düsseldorf in charge of infringement proceedings in Germany based on the patent in suit have all requested acceleration of the proceedings.

Finally, the subject-matter concerned is not so complex that the parties and the Board cannot understand the objections, and the respondent-patent proprietor has not requested remittal.

For all these reasons, the Board decides to examine this objection in the appeal proceedings and not to remit the case to the department of first instance.

5. Added subject-matter (Article 100(c) EPC)

The intervener and the appellant-opponent considered that the subject-matter of claim 1 was an unallowable intermediate generalisation. Claim 1 did not include all the essential features of the embodiments of Figures 103 to 105. The general part of the description, in particular paragraphs [0031] and [0036] (of the published version of the application), could not be used as a basis for the subject-matter claimed because not only did the two paragraphs refer to different, separate embodiments, but paragraph [0036], by referring to the inward movement of the needle trap and arm for the releasing of the catheter hub, unequivocally implied the presence of an inner recess in the catheter hub.

The Board does not share this opinion, for the following reasons.

The general part of the description has to be considered. In the application as filed, the problems met in prior art devices are summarised as follows (paragraph [0016] of the application as published): "*The basic problem with many of the present day safety hypodermic devices is that they are meant to be manually activated, or in the language of the medical device industry, they are considered "active" devices. They may have safety shields, retractable needles, moveable sheaths or the like; but they generally require the user to complete another procedure to facilitate engagement of the safety mechanism.(...)*"

The following paragraphs [0018] to [0030] mention several objects of the invention, with paragraphs [0019] and [0030] being of particular interest in the present case:

[0019]: "*It is another object of this invention to provide a safety hypodermic apparatus which is automatic and/or semiautomatic covering, fail-safe and single-use in nature.*"

[0030]: "*It is yet another object of the invention to prevent catheter separation from the catheter carrying device until the needle tip is safely contained in a protective cover.*"

Paragraph [0030] is followed by paragraphs [0031] to [0036], which present the embodiments, or more specifically explain how the objects of the invention are achieved, in general terms. While the words "in an embodiment", "in another embodiment", "in yet another embodiment" or the like are used to introduce the different solutions, these paragraphs must be seen as answers to the different objects of paragraphs [0018] to [0030], and not as specific individual embodiments excluding each other or incompatible with each other. This is confirmed by the very specific embodiments described later in the specification, which for the most part combine the teachings of several of these paragraphs. For instance, the embodiment according to Figure 103 (falling under the wording of claim 1) includes at least the teachings of paragraphs [0031], [0032], first sentence, and [0036].

From this general part it appears that it cannot have been the intention in the application as filed to

present non-combinable embodiments in these general paragraphs, as alleged by the appellant-opponent and the intervener. It follows that, for the purpose of determining if there is added subject-matter, for the person skilled in the art reading the application as a whole, the teachings of these paragraphs can unambiguously be combined, as long as there is no technical incompatibility.

Of particular interest for the present case are paragraphs [0031] and [0036] as mentioned by the appellant-opponent and the intervener. Paragraph [0031] is about the presence of a needle trap biased against or towards the needle, which entraps the needle tip once moved beyond the needle tip, so it appears to be the answer to the object of the invention as presented in paragraph [0019] (it also mentions the tether, as a forward movement limiting means). Paragraph [0036] appears to be the answer to the object of the invention as presented in paragraph [0030], in that it is about a coupling mechanism preventing mechanical separation from the catheter until the needle tip is safely contained within the needle trap. The relevant passage of paragraph [0036] mentioned by the appellant-opponent and the intervener reads as follows: "*In one embodiment, the coupling mechanism includes an arm having a proximal end and a distal end. The proximal end of the arm is attached to the movable needle trap. The distal end of the arm includes a projection that is releasably retained within a recess of a catheter hub. Hence, as the needle trap moves inward to entrap the needle tip, the arm also moves inward. The inward movement of the arm causes the arm's distal projection to be released from the catheter hub recess, thereby permitting a separation between the needle guard assembly and the catheter hub.*"

The appellant-opponent and the intervener considered that the wording of this latter passage unequivocally implied that the recess must be an inner recess.

The Board does not share this opinion. Firstly it is to be noted that the relevant passage does not mention an inner recess, but more generally a recess. Secondly, what this passage explains is that an arm having a distal end and a proximal end is attached to the movable needle trap, and that the distal end of the arm includes a projection retained in a recess of the catheter hub. It goes on to explain that, the arm being attached to the needle trap, when the latter moves inwardly (towards the needle axis due to it being biased towards the needle) to entrap the needle tip, the arm follows that movement and releases the projection at the distal end of the arm. In other words, this paragraph explains that due to the arm being attached to the needle trap and the projection being at the distal end of the arm, there is an intrinsic link between the needle trap, the arm and the projection, which results in a common movement of all three elements to free the catheter hub at the same time as the needle trap gets into its protecting position in front of the needle tip. Hence, this satisfies at least the object of the invention under paragraph [0019] to provide a safety hypodermic apparatus which is automatic and/or semiautomatic covering in nature, and the object of paragraph [0030], which is to prevent catheter separation from the catheter carrying device until the needle tip is safely contained in a protective cover.

This intrinsic link is also mentioned in the parts of the description which explain the specific embodiments with an intravenous catheter. For instance, in relation

to Figure 103, in paragraph [0179], column 41, lines 21 to 25: "...*said needle trap 41 having a movable arm 45 and projection 42 for releasably retaining a catheter hub 13 from said male section 78 after insertion of the catheter 29 into a patient*." or in paragraph [0186] in relation to the embodiment of Figure 105, where this intrinsic link between the movement of the needle trap, the arm and the projection is almost explicitly mentioned: "...*showing the needle tip 11 being safely contained within the needle guard 22a with the arm 45 and projection 42 correspondingly moved inwardly and activated with the needle trap 41...*". Several additional passages in the detailed description include the same kind of statement. It should also be noted, that, when looking at Figure 105, the very part of the needle trap in contact with the needle before the entrapment of the needle tip lies beyond the needle axis in the protecting position shown. Hence, this very part of the needle trap has also moved outwardly after having crossed the needle axis during the movement bringing the needle trap to its rest position shown in that figure. This is an additional indication as to why it cannot be argued that when in the application as filed the adverb "inwardly" is used in paragraph [0036], this was meant to designate a "pure" inward movement, or an inward movement only.

Hence, the teaching of paragraph [0036] is that there is an intrinsic link between the movements of the needle trap, the arm attached to the needle trap and the projection on the arm. Nothing more limiting about the recess can be concluded from this paragraph, when read in context.

Therefore, when read with the application as a whole in mind, paragraphs [0031] and [0036] are an unambiguous

general basis for claim 1, so that Article 100(c) EPC does not prejudice the maintenance of the patent as granted.

In view of the above, since paragraphs [0031] and [0036] form a sufficient basis for claim 1, other objections pursuant to Article 100(c) EPC raised in the written proceedings and based on specific features of the specific embodiments allegedly not taken over into claim 1 are not relevant. It is noted that they were not pursued at the oral proceedings either.

6. Admissibility of the alleged prior uses

At the oral proceedings, the appellant-opponent and the intervener wanted objections of lack of novelty of the subject-matter of claim 1 over three prior uses to be examined. Hence, it was first necessary to assess whether these prior uses were in the proceedings or were to be admitted into the proceedings.

6.1 Admissibility of the alleged "Guardian Design" prior use

Since the intervention took place in the appeal-opposition proceedings, pursuant to G3/04 (point 10 of the reasons) the intervener has the same status as a non-appealing party pursuant to Article 107 EPC. Therefore the RPBA also apply to the intervener.

The alleged "Guardian Design" prior use had been considered late-filed by the Opposition Division and disregarded. It was re-introduced by the intervener in its notice of intervention (Facts and Submissions, point IV). As can be seen, the intervener referred to this alleged prior use by simply citing the former documents (filed by the appellant-opponent in the opposition

proceedings) and making a general reference to the earlier respective submissions of the same appellant-opponent, in other words, the submissions filed during the opposition proceedings. No further substantiation was provided in the notice of intervention. According to the established case law of the boards of appeal, such general references to other submissions are not considered to be a proper substantiation of the objection raised, because it cannot be left to the Board or the other party/parties to find out what the line of argument of the intervener actually was. This is particularly true for alleged prior uses for which the relationships between the different pieces of evidence have to be assessed.

Hence, any substantiation presented by the intervener later on in the proceedings has to be considered late-filed and a change of its case.

After filing its notice of intervention and prior to the oral proceedings, the intervener did not file any further written substantiation of this prior use. It was only at the oral proceedings that the intervener wished to discuss it or, in other words, to complete its substantiation.

Alleged prior uses are a complex matter to examine, as features of the object that has allegedly been shown have to be determined, and their availability to the public scrutinized. Such examination cannot be started at oral proceedings, when neither the other parties nor the Board have prepared for it, because up to that point, they had no reason in the file to do so. This is a typical situation dealt with under Article 13(3) RPBA, because neither the other parties nor the Board can reasonably be expected to deal with such an amendment of

the intervener's case without the oral proceedings being adjourned.

The Board therefore decides not to admit the alleged "Guardian Design" prior use into the proceedings pursuant to Article 13(3) RPBA.

6.2 Admissibility of the other two prior uses

With letter of 11 September 2015 the appellant-opponent filed evidence for two further prior uses. He submitted that he had conducted "discovery proceedings according to 28 U.S.C. § 1782 in the United States" against InjectiMed Inc. and its president Mr. Thomas C. Kuracina, co-inventor of the patent in suit.

According to the findings, two public prior uses had taken place, one on 18 November 1996 and one on 27 November 1996:

1) the submission of engineering drawings according to Figure 35 of priority document P3 to Sherwood-Davis & Geck as an attachment to a letter dated 27 November 1996 (exhibit 12.5),

2) the demonstration of eight working prototype versions of the indwelling catheter according to Figures 19 and 35 of P3 to two employees of Johnson and Johnson Medical, Inc. on 18 November 1996.

According to the appellant-opponent the subpoena was sent to Mr Kuracina on 22 May 2015, and the final decision of the US court on which of the documents must be considered confidential and which not was taken on 4 September 2015. The documents were filed with the EPO on 11 September 2015, so that, according to the appellant-

opponent there was no lateness. In addition, the disclosed devices were according to Figure 103 of the patent in suit, so that they were more relevant than the documents on file.

6.2.1 Sherwood-Davis & Geck

According to the appellant-opponent, engineering drawings representing the embodiment of Figure 35 of P3 were attached to a letter (exhibit 12.5) written by Mr Gordon (of InjectiMed Inc.) and sent to Mr Vacca (of Sherwood-Davis & Geck) on 27 November 1996.

In the Board's opinion, while at the end of the first page of the letter, it is mentioned that "*our new design will not allow separation of the catheter hub from the needle guard until the needle point is completely trapped and safe from needle stick injury*", and engineering drawings and artist's renditions are mentioned (at the end of the second page of the letter) as being enclosed, no specific features of the new design are described in the letter, and the drawings or artist's renditions mentioned were not filed by the appellant-opponent. It follows that on the basis of this evidence it is, prima facie, not possible to know what the constructive features of the product mentioned in the letter were. In addition, Mr Kuracina stated (pages 133 and 134 of his deposition (exhibit 12.1)) that he was not aware of the existence of engineering drawings.

In view of the absence of any plausible evidence as to the features of the device mentioned, the Board decides not to admit the prior use into the proceedings pursuant to Article 13(1) RPBA.

6.2.2 Johnson and Johnson Medical, Inc.

This prior use concerns the alleged disclosure of prototypes of the IV catheters according to Figures 19 and 35 of P3. In P3, at the top of page 49, it is mentioned that prototype versions of an IV catheter according to Figures 19 and 35 were manufactured on 10 October 1996 with a through hole instead of an annular recess for retaining the projection of the arm in the hub. On the same page 49, it is stated in the last but one paragraph that "*Eight welded working prototype samples were demonstrated and disclosed to Johnson & Johnson Medical, Inc. on 18 November 1996 by John R.Gordon of InjectiMed.Inc. Wiley Green and Brian Blischak, both of Johnson & Johnson Medical Inc., were present at the meeting*."

Furthermore, in exhibit 12.11, presented as being a report on the meeting of 18 November 1996, the manufacturing of an annular ring in the catheter hub appears to have been discussed.

Hence, prima facie, if confirmed, this alleged prior use IV catheter assembly might have all the features of claim 1.

The respondent-patent proprietor considered that this alleged prior use should not be admitted into the proceedings because the information on the prototypes and demonstrations was in the priority document, and was thus present right from the start of the opposition proceedings, so the appellant-opponent could have invoked it earlier. The appellant-opponent did not even mention its intention in the statement setting out the grounds of appeal filed on 15 April 2015, and did not actually start the discovery proceedings in the US until 28 April 2015.

In the Board's opinion, while it is true that the demonstration of the prototypes by Mr Gordon is mentioned in priority document P3, which was in the file right from the beginning of the opposition proceedings, in the present case it considers that the relevance of the prior use, which would be the most relevant piece of prior art if proven to have been shown, outweighs the lateness of its filing. Apart from the fact that the appellant-opponent might genuinely have thought that the patent would be revoked in the first instance on the basis of the patent documents on file in the opposition proceedings, the prior use was not a prior use by itself, but by the respondent-patent proprietor, so was in any case more difficult to establish. The proceedings in the USA appear to have been conducted swiftly, and the appellant-opponent filed the result of these proceedings with the EPO as soon as it could after having received them. Moreover, as mentioned, the alleged prior use concerned is by the respondent-patent proprietor itself, so that it cannot a priori pretend to have particular difficulties establishing the circumstances under which it occurred.

For the above reasons, the Board decides to introduce the alleged prior use at Johnson and Johnson Medical, Inc. into the proceedings pursuant to Article 13(1) RPBA.

7. Novelty

7.1 In view of the prior use at Johnson and Johnson Medical, Inc.

As already mentioned, this alleged prior use is essentially based on page 49 of priority document P3,

the deposition of Mr Kuracina (exhibit 12.1), the report on the meeting of 18 November 1996 (exhibit 12.11) and the presentation given on 27 March 1997 to Johnson and Johnson Medical, Inc. (exhibit 12.12).

Before assessing the alleged availability to the public, the Board wishes to concentrate on the features allegedly disclosed.

On page 49 of P3, the first full paragraph reads as follows: "*Working prototype versions of the indwelling catheter invention disclosed and described in this application in Figures 19 and 35 were manufactured by Thomas C. Kuracina on 10/10/96 by assembling a number of molded components, using a flexible tether.*"
In the middle of the second paragraph it is stated that: "*...The catheter hub 13' was releasably held adjacent to the catheter adapter 78 by means of a through hole (rather than the annular recess 32 shown through out this application) in the catheter hub 13' wall section ...*"
Finally, the third full paragraph of the same page reads as follows:
"*Eight welded working prototype samples were demonstrated and disclosed to Johnson & Johnson Medical, Inc. on 18 November 1996 by John R.Gordon of InjectiMed, Inc. Wiley Green and Brian Blischak, both of Johnson & Johnson Medical Inc. were present at the meeting.*"

Exhibit 12.11 is a one-page report on the meeting of 18 November 1996 written by Mr John Gordon. The relevant passage is headed "NOTE" and reads as follows: "*The one area of conjecture revolved around our implied ability to mold-in an annular ring in the Catheter Hub, without going to a split mold. I assured them that while I knew little of nothing about molding, that C&R was confident*

of their ability to mold-in the ring in a straight-pull molding operation. This has been re-affirmed by Craig and Randy."

In the final paragraph of this report it is stated that samples of a molded-in annular ring in a Luer hub should be available at the next meeting.

In his deposition, Mr Kuracina indicated several times that he had manufactured multiple prototypes, and so could not be sure of the precise constructive features each of them had (for instance, page 50, line 25 to page 51, line 3: "*I manufactured multiple prototypes of multiple platform needles and this is just one of those prototypes.*" or page 83, lines 17 to 19: "*There were so many products and I don't know exactly which ones, what versions were submitted.*", pages 147 – 151, etc.), and that at the time of his declaration no prototype of the IV catheter from 1996 existed anymore (page 162).

The slide of the presentation of 26 March 1997 (exhibit 12.12) on page TK0000151 shows an IV catheter with a needle guard and a releasing mechanism for releasing the catheter hub whereby the projection on the arm (attached to the needle trap) is retained behind an undercut (not a recess). This undercut is also designated "undercut" on the drawing.

According to the appellant-opponent and the intervener, the statements on page 49 of P3 were sufficient to determine the features of the IV catheter manufactured as a prototype and shown to Johnson and Johnson Medical, Inc. The report on the meeting held on 18 November 1996 showed that the option of having a recess in the hub was discussed at that very meeting, which would in itself be a disclosure anticipating the subject-matter of claim 1.

The Board does not share this opinion. For a prior use to be considered established, this has to be the case beyond any reasonable doubt (T 0782/92). In the present case, the Board firstly notes that the relevant meeting was held in November 1996, almost 20 years before the oral proceedings before the Board, and that there is no deposition on file by any of the persons having directly participated in that meeting. Secondly, prototypes are generally made to assess the workability of some technical concept, so that they do not necessarily reproduce all the features of the intended finished product. This is confirmed by Mr Kuracina on page 52, lines 5 to 8, of his deposition when he was asked if the said figure referred to on page 49 of P3 was Figure 19: "*Clearly this does not indicate that every feature of in the drawings were included in the prototype and that's what I have to say about that.*" What exactly the prototypes were made for is not mentioned in the first paragraph of page 49 of P3, where, as already stated, it is only mentioned that (several) working prototype versions of the indwelling catheter invention disclosed in this application in Figures 19 and 35 were manufactured. What is mentioned is that the tether was flexible, and, according to the middle sentence of the second paragraph, that there was no annular recess, but a through-hole instead. Hence, apart possibly from other constructive features, at least the annular recess appears not to have been present in the prototype versions.

The appellant-opponent considered that this was in any case disclosed by the report on the meeting (exhibit 12.11).

The Board does not share this view, since the relevant paragraph of the report was about conjecture around the ability to mold-in an annular ring without going to a split mold. Whether or not the annular ring referred to in that report was the annular recess shown on Figure 19 is also not apparent from the report. Moreover, P3 mentions several times that the retaining element in the catheter hub could be an inner channel, recess, slot or undercut (page 31, page 33, page 40, page 42, etc.). It follows that when the report mentions an annular ring, it is not clear whether it means one of these elements, and if so, which one, or whether it means something else entirely. On top of that, the report (exhibit 12.11) makes no reference at all to either Figure 19 or Figure 35 of P3, so that there is no direct link to these embodiments apparent from that report. Additionally, and independently of the report, the undercut in the catheter hub of the IV catheter shown in a presentation at Johnson and Johnson Medical, Inc. sometime later (the drawing presented on page TK0000151 of exhibit 12.12), while clearly not a recess, can technically be designated an annular ring, which casts additional doubt on the likelihood of a recess being discussed at the meeting on 18 November.

It follows that it is not possible to determine without any reasonable doubt, what was disclosed at the meeting Mr Gordon had at Johnson and Johnson Medical, Inc.

For the above reasons alone, the prior use of an IV catheter according to Figure 19 or Figure 35 is not established, so that it is not established that an IV catheter according to claim 1 was shown at the meeting with Johnson and Johnson Medical, Inc. For these reasons, it is also not necessary to examine whether or not the disclosure was confidential, the subject-matter

of claim 1 being in any case novel over the alleged prior use.

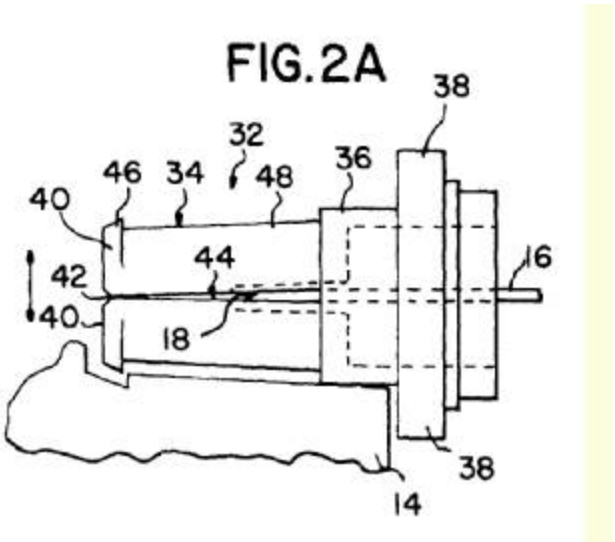
7.2 The intervener and the appellant-opponent considered that the subject-matter of claim 1 lacked novelty over D3, D2 and D1.

7.2.1 Before going into the details of the novelty analysis, the Board would like to clarify the following:

According to feature g) of claim 1, the coupling mechanism should comprise an arm (45) having a proximal end and a distal end, the proximal end of the arm being attached to the movable needle trap (41), whereby the distal end of the arm (45) should include a projection (42) that is releasably retained with the catheter hub (13).

In the opinion of the Board, for the person skilled in the art, a normal understanding of the shape of an arm having a proximal end and a distal end would be an elongate body with a (defined and recognisable) beginning and a (defined and recognisable) end. In the absence of any other deviating definition in the patent in suit, and given on the contrary a confirmation of this definition in the figures showing such an arm, this is the definition to be considered when assessing the novelty of the subject-matter of claim 1. By the same token, when the wording of the claim requires that the arm be attached to the needle trap, a bona fide reading of this feature implies the presence of two recognisable elements, namely a needle trap and an arm. Here again, the description of the patent does not suggest a different definition.

7.2.2 The intervener and the appellant-opponent suggested that separate recognisable elements would not have to be present, and that it would be enough if the wording of the claim could be read on the prior art. For that reason they considered that the embodiment shown in Figure 2A of D1 would be novelty-destroying for the subject-matter of claim 1.



This figure shows resilient fingers 32 forming a kind of pincers. The distal end of each of the fingers 32 is provided with a detent 46 extending radially outwardly from each of the fingers' bodies and fitting within corresponding recesses 50 within the catheter hub. The fingers close after the needle tip has passed: "*As shown in Figure 2(a), when the cannula 16 is withdrawn from the catheter such that the tip 18 is positioned within the chamber 44, the spring biasing of the fingers 34 causes the distal ends 40 to again contact each other at 42 with the cannula tip 18 secured within the closed chamber 44.*"(column 4, lines 41 to 46). The chamber 44 is shown in Figure 2A by dashed lines. In the same figure, the distal end of the chamber 44 appears to end proximally from the distal end of the fingers. This appears also to be mentioned in column 2, lines 47 to

49: "*An addition, each of the fingers has a channel extending from the base to a location spaced from the distal end of the fingers.*"

From the above, the intervener and the appellant-opponent concluded that the part of the fingers going up to the distal end of the chamber 44 can be seen as the needle trap and the part of the fingers going from the distal end of the chamber 44 to the distal end of the fingers can be seen as arms, in which case the detent 46 would be at the proximal end of the arm, thereby anticipating the corresponding features of claim 1.

On the basis of the interpretation set out above, the Board does not share this opinion. In the opinion of the Board, the person skilled in the art looking at Figure 2A and the corresponding description would conclude that there are two or more fingers forming a chamber suitable for accepting the needle tip, whereby the distal ends of the fingers have detents fitting in recesses in the catheter hub. It is possible that each of the fingers taken as a whole could technically be designated as an arm, but certainly not as two elements, namely as a needle trap with an arm attached to it.

Moreover, even though the dashed lines showing the chamber 44 seem to stop more or less in the middle of the fingers, suggesting that there is some distance between the distal end of the chamber and the distal end of the finger, this information is only visible on Figure 2A and not on any of the other Figures 4 to 7 showing a similar embodiment. It follows that no other part of D1 confirms the presence of this distance.

For these reasons, the Board considers that D1 does at least not disclose a needle trap with an arm attached to

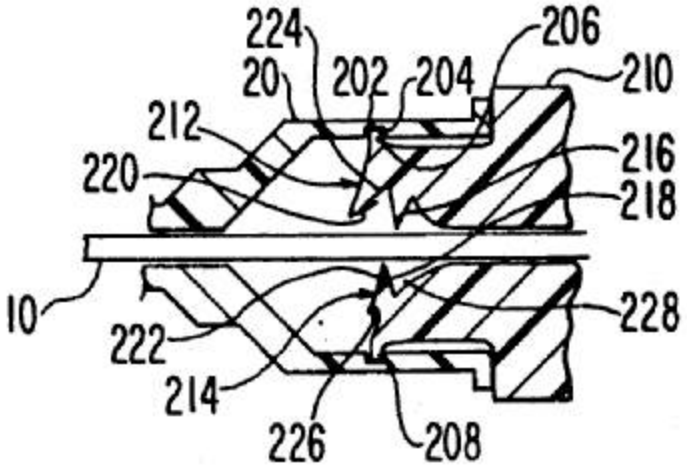
it, whereby there is a projection on the distal end of the arm.

The other ways of interpreting the figures of D1 presented by the appellant-opponent and the intervener in the written proceedings were not pursued at the oral proceedings; in any case, they suffered from the same deficiencies.

7.2.3 The objection of lack of novelty based on D3 fails for at least the same reasons.

The appellant-opponent and the intervener submitted that the embodiment according to Figures 11 and 12 disclosed a needle trap with an arm attached to it, whereby the arm had a projection on its distal end.

FIG. 11



In this embodiment a "*distal end cap 210 includes a pair of needle jaws 212 and 214 which have flexible pincers 216, 218 with contact surfaces 220, 222 formed as intermeshing, complementary, saw-tooth surfaces. Included in the saw-tooth surfaces are latch locks 224*

and 226 that lock needle jaws 212, 214 together when needle 10 is fully withdrawn from needle passageway 228. [...] Latch locks 224, 228 snap together and lock the intermeshed, saw-tooth surfaces." (column 7, lines 42 to 54). In the figures, it can be seen that one of the jaws is provided at its distal end with so to say one saw tooth, and the other jaw is provided with two teeth, so that, in the protecting closed position, the single saw tooth of the one jaw comes to lie between the two saw teeth of the other jaw, such that they intermesh. At the distal ends (and radially outwardly) of the needle jaws 212, 214 latch flanges 206, 208 are present to retain the jaws in a hub channel 202 or catch rib before the needle is withdrawn (column 7, lines 39 to 41: "*The proximal channel wall 204 acts as an interior catch rib for end cap latch flanges 206 and 208.*").

The appellant-opponent and the intervener considered that, at least, on the jaw having two teeth, the distance between the distal end of the first tooth to the distal end of the jaw (hence the breadth or width of the second tooth) can be seen as an arm with a projection on its distal end, which would anticipate the corresponding feature of claim 1.

In the opinion of the Board, what comes out of these figures and their description is that they appear to show and describe a very specific embodiment in which two jaws are released from the catheter hub once the needle is withdrawn and that these two jaws interconnect, even lock together, in their protecting position. The Board does not see how the person skilled in the art reading this disclosure could possibly recognise two elements, namely an arm (elongate with a distal end and a proximal end) attached to a needle trap, the arm having a projection on its distal end. The

Board considers that a technically meaningful reading of these figures would lead the person skilled in the art to recognise a very specific needle tip protection system with intermeshing teeth to entrap the needle tip, but not the two elements as claimed.

Hence, the subject-matter of claim 1 is not anticipated by D3 for that reason alone.

7.2.4 Novelty over D2

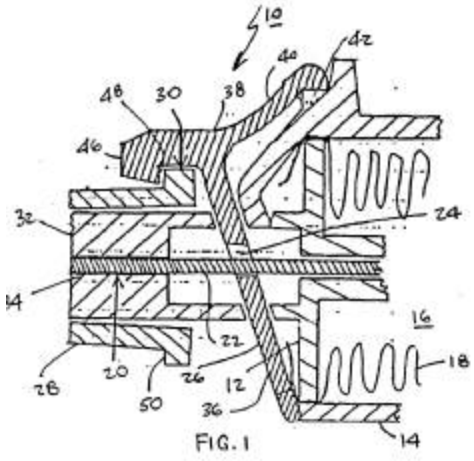


FIG. 1

In the Board's opinion, in relation to D2 the question of the disclosure of a recess appears to be critical.

The way of working of the embodiment disclosed in D2 is different from those disclosed in D1 or D3, because in the IV catheter according to D2 the catheter hub is not released from the inside, as in the embodiments of D1 and D3, but from the outside. The T-shaped structure 38 shown there includes the plate portion 36 covering the needle tip in the protecting position. This T-shaped structure has its own spring (bending) action, as can be seen in Figures 1 and 2, and read in column 7, lines 15 to 27. One of the arms of the T-shaped structure includes a hook-like projection 46 forming a recess 48

into which there engages a lug or flange of a Luer lock forming an integral component of the catheter hub 28 so as to maintain the components in their interlocked condition as shown in Figure 1 of the drawings (column 7, lines 2 to 8). The protecting mechanism functions as follows (column 7, lines 15 to 27): "*As the cannula 22 is retracted from the catheter through the central aperture 24 in the plate portion 36 of the latching element 26 for the catheter hub 28, the spring or biasing action of the plastic material of the T-shaped structure causes it to pivot or bend at location 54 so as to cause the aperture 24 to be displaced upwardly and the plate portion 36 forming a barrier preventing the tip of the retracted cannula 22 from extending beyond the nose guard portion of the housing. Simultaneously, the bending action of the plate portion 36 disengages the Luer lug 50 from the recess 48 in the opposite arm 44 of the T-shaped element, resultingly releasing the catheter hub 28 and...*"

As can be understood from the above, in this embodiment the catheter hub retaining element is a hook-like element retaining the catheter hub behind the flange or lug of the Luer lock.

The appellant-opponent and the intervener considered that the word "recess" in claim 1 had to be understood in a broad sense and that in D2 the smaller diameter portion of the hub together with the flange having a bigger diameter defined a recess as well.

In the Board's opinion, such a difference of diameter does not fall under the normal technical definition of a recess. The person skilled in the art would not consider that a flange defines a recess. A recess is rather a depression or deepened part interrupting a continuous

surface, as opposed to a protrusion or elevated part interrupting such a surface. No other definition than the normal definition of a recess appears to be present in the patent in suit. On the contrary, the embodiment according to Figure 121, for instance, shows an elevation on the inner surface of the catheter hub as a retaining means, which is defined in the corresponding description part (paragraphs [218] to [222]) as being an undercut. In the language of the patent in suit, the flange of D2 would therefore rather come close to an undercut.

It follows that, at least for this reason, D2 does not anticipate the subject-matter of claim 1.

For the reasons above, the subject-matter of claim 1 is novel, so that the ground for opposition pursuant to Article 100(a) EPC in combination with Article 54 EPC does not prejudice the maintenance of the patent as granted.

8. Inventive step

Although the validity of the priority was disputed among the parties, the Board decided to consider the lack of inventive step objections based on D1 and D2 (intermediate documents under Article 54(3) EPC in case of validity of the priority). None of the parties objected to this.

8.1 The appellant-opponent and the intervener raised the following lines of argument in relation to the objection of lack of inventive step:

D2 or D3 alone; D2 in combination with D3 or D1; D3 in combination with D2 or D16; all latter lines of argument

possibly in combination with D4, if the tether was considered a differentiating feature.

8.2 Admissibility of the line of argument based on D16

The intervener considered that it was sufficient for the admissibility of a line of argument based on D16 for this document to be mentioned in the notice of intervention.

The Board does not share this opinion. In the notice of intervention (Facts and Submissions, point IV), the only sentence which includes a reference to D16 is the following: "*Appellant-opponent II relies on all documents D1 – D18 filed with the notice of opposition of Appellant-opponent I.*" This is by no means a substantiated line of argument based on a combination of D3 with D16 meant to be presented at the oral proceedings. As already mentioned above in relation to the Guardian Design prior use, oral proceedings are not the time to present new lines of argument or objections not submitted in the written proceedings. The examination of such new lines cannot be started at oral proceedings, when neither the other parties nor the Board are prepared, because up to this point, D16 has played no role in the appeal proceedings. This is a typical situation dealt with under Article 13(3) RPBA, because neither the other parties nor the Board can reasonably be expected to deal with such an amendment of the intervener's case without the oral proceedings being adjourned.

The Board therefore decided not to admit the line of argument based on D16 into the proceedings pursuant to Article 13(3) RPBA.

8.3 Starting from D2

According to the appellant-opponent and the intervener, it would be obvious to add a distal wall on the outside surface of the catheter hub, so as to create a recess for the hook part of the T-shaped structure 38, if this was needed, or to integrate a recess into that outside surface. This would be an obvious kinematic inversion.

The Board does not share this opinion. In D2, it is clearly indicated that the flange is from a Luer lock mechanism (column 7, lines 2 to 8). Hence, changing the shape of the flange or the catheter hub in the close vicinity of the flange would mean being unable to use the Luer-lock connectability anymore. This connectability is explicitly mentioned in column 7, lines 23 to 36: *"....so as to provide for the capability of connecting a cooperating Luer lock structure (not shown) to the catheter hub 28 enabling the administering of parenteral fluids, blood or medications to the patient through the catheter in the venipuncture which remains attached to the catheter hub 28."*. The Board does not see any reason why the person skilled in the art would (obviously) be prepared to lose this normal, commonly known and used connectability of this IV catheter. On the contrary, the person skilled in the art would be at pains to keep such standard connectability, because it makes the product compatible with existing connectors on tubes or other devices meant to be connected to the IV catheter. It is thus not an obvious step to abandon it.

It is also not realistic to consider that the person skilled in the art would (obviously) change the retaining mechanism shown in D2 to an alternative inner retaining mechanism as presented in D3. The mechanism of

D2 has the advantage of being able to use a standard catheter hub with a standard Luer lock, whereas changing to inner retaining means implies manufacturing a special catheter hub including such inner retaining means. This is not an obvious amendment. In addition, even if the person skilled in the art might adopt the retaining mechanism of D3, he would not necessarily come to the subject-matter of claim 1, because, as mentioned above, in D3 there are no arms attached to a needle trap.

8.4 Starting from D3

The embodiment of D3 (Figures 11, 12), which is considered to be the closest prior art, has already been described above. The closing mechanism with the two needle jaws having complementary indentations (saw-tooth needle jaws) is a very specific construction. These complementary elements are even said to be locked together once the needle is withdrawn (column 7, lines 45-48 and 53, 54: "*Included in the saw-tooth surfaces are latch locks 224 and 226 that lock needle jaws 212, 214 together when needle 10 is fully withdrawn from needle passageway 228*"; "*Latch locks 224, 228 snap together and lock the intermeshed, saw-tooth surfaces*".). As already indicated, on each of these needle jaws' distal ends there is a projection (latch flanges 206, 208) retained in an interior catch rib.

According to the appellant-opponent and the intervener, it would be an obvious alternative to place these latch flanges or projections on arms extending from the needle jaws, if this was needed, e.g. for increasing the lever useful for releasing the projection. Such alternative was additionally suggested by the embodiment of Figures 17 to 21 of D3 itself.

The Board does not share this opinion. Apart from the specific way of working as already described, the IV catheter shown in Figures 11 and 12 of D3 has the specificity that the retaining mechanism and the needle jaws (or needle trap) are all inside the catheter hub, which makes it a very compact device. Adding arms to the jaws would go against this compactness, so that the Board considers that it would not be an obvious step to prolong the jaws in such a way. The embodiment according to Figures 17 to 22 does not change this assessment. On the contrary, even if the person skilled in the art considered applying some of the teachings of this embodiment to that of Figures 11 and 12, he would not come to the embodiment of claim 1. Indeed, even though the embodiment of these figures work with arms 450 and 452, their latch surfaces 460 and 462 (or projections) cooperate with an internal rib 392 (not a recess) and the safety mechanism must be actuated by the operator (column 8, lines 26 to 29: "*Upper and lower operator tabs 424 and 426 are provided on the end cap such that the operator can transversely compress tabs 424 and 426.*"; column 8, lines 54 to 58: "*Due to the transverse compression of operator tabs 424 and 426, latches 460 and 462 have been uncoupled from internal rib 392.*") in order to free the catheter hub and protect the needle tip, contrary to what happens in the claimed IV catheter, in which the needle trap is biased towards the needle shaft, and then automatically entraps the needle tip once the latter has passed the needle trap during the withdrawal of the needle.

The Board wishes to emphasise that, when starting from D3, the provision of arms at the distal ends of the needle trap is not a simple alternative. The arms allow the needle guard to be positioned outside the catheter hub and therefore allow for more freedom in designing

it. Indeed, as mentioned above, the protecting mechanism of D3 (Figures 11 and 12) is entirely contained in the catheter hub, which is good for compactness, but limits the possible designs because of the reduced space available. By providing the needle jaws with arm extensions, the essential parts of the protecting mechanism can be placed outside the catheter hub and thus be allowed to have a variety of designs without being limited by the reduced space inside the catheter hub.

Hence, the objective problem can be seen as one of increasing the options for the design of the needle guard.

As demonstrated above, the subject-matter of claim 1 is not obvious when considering D3 alone. The same is also true when additionally considering the teaching of D2. While in D2 the needle guard is, as already established, outside the catheter hub, its way of functioning is based on a different concept, namely that of retaining a "standard" catheter hub with a hook-like arm acting on a standard flange of a Luer lock, not on a recess. Hence, D2 cannot render the subject-matter of claim 1 obvious either.

8.5 For the reasons given above, the subject-matter of claim 1 is inventive, so that the ground for opposition pursuant to Article 100(a) EPC in combination with Article 56 EPC does not prejudice the maintenance of the patent as granted.

9. As already indicated, documents D1 and D2 could be prior art pursuant to Article 54(3) or 54(2) EPC depending on the validity or not of the priority P3 of the patent in suit. Since, however, as demonstrated above, the

subject-matter of claim 1 was inventive even if D1 and D2 were documents pursuant to Article 54(2) EPC, the validity of the priority P3 did not have to be examined by the Board.

Order

For these reasons it is decided that:

1. The appeal is dismissed.

2. The intervention is rejected.

The Registrar: The Chairman:

D. Hampe E. Dufrasne

Decision electronically authenticated