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Datasheet for the decision of 7 November 2014

Case Number: T 1166/10 - 3.2.02

Application Number: 02025277.1

Publication Number: 1316325

IPC: A61M5/32

Language of the proceedings: EN

Title of invention:
Needle safety device

Patent Proprietor:
Becton Dickinson and Company

Opponent:
Costantini, Paul

Headword:

Relevant legal provisions:
EPC R. 99(2), 49(10), 139
EPC Art. 123(2), 111(1)
RPBA Art. 12(2), 13(1)

Keyword:
Admissibility of appeal (yes)
Late-filed auxiliary requests - admitted (yes)
Amendments - added subject-matter (no) -
correction of errors (yes)
Appeal decision -
remittal to the department of first instance (yes)

Decisions cited:

Catchword:

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Case Number: T 1166/10 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 7 November 2014

Appellant: (Patent Proprietor)	Becton Dickinson and Company One Becton Drive Franklin Lakes, NJ 07417-1880 (US)
Representative:	Molnia, David Df-mp Dörries Frank-Molnia & Pohlman Patentanwälte Rechtsanwälte PartG mbB Theatinerstrasse 16 80333 München (DE)
Respondent: (Opponent)	Costantini, Paul 16 Rue Rabelais 91800 Brunoy (FR)
Representative:	Cabinet Plasseraud 52, rue de la Victoire 75440 Paris Cedex 09 (FR)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 28 May 2010 revoking European patent No. 1316325 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	E. Dufrasne
Members:	C. Körber
	P. L. P. Weber

Summary of Facts and Submissions

I. On 28 May 2010 the Opposition Division posted its decision revoking European patent No. 1316325 for non-compliance of the main request with the requirements of Article 123(2) EPC. The auxiliary requests were not admitted into the proceedings.

II. An appeal was lodged against this decision by the patent proprietor by notice received on 1 June 2010, with the appeal fee being paid on the same day. The statement setting out the grounds of appeal was received on 6 October 2010.

III. By communication of 25 August 2014, the Board forwarded its provisional opinion to the parties and summoned them to oral proceedings.

IV. By letter of 3 November 2014, the respondent (opponent) indicated that it would not attend the oral proceedings.

V. Oral proceedings were held on 7 November 2014 in the absence of the respondent in accordance with Rule 115(2) EPC and Article 15(3) RPBA.

The final requests of the parties were as follows:

The appellant (patent proprietor) requested that the decision under appeal be set aside and that the patent be maintained on the basis of the first auxiliary request filed during oral proceedings or, in the alternative, of one of the second to fourth auxiliary requests filed with letter dated 10 October 2014, or one of the first to fourth auxiliary requests filed with the statement setting out the grounds of appeal.

Both main requests were withdrawn during oral proceedings.

The respondent (opponent) had requested in writing that the appeal be rejected as inadmissible or, in the alternative, that the appeal be dismissed.

VI. Claim 1 of the first auxiliary request filed during the oral proceedings reads (with the feature denotation proposed in the statement of grounds of appeal indicated in the left margin):

A) "A shieldable needle assembly (10) and a needle holder (12) unitary or integral with a portion of the needle assembly (10), wherein the needle assembly comprises:

B) a needle cannula (22) having a proximal end (34) and a distal end (36); a hub (24) mounted to said needle cannula (22) at a location spaced from said distal end (36) of said needle cannula (22);

C) a substantially tubular housing (80) at least a portion of which projects distally from said hub (24) toward said distal end (36) of said needle cannula (22);

D) a safety shield (28) telescoped over said needle cannula (22), said safety shield (28) having opposite proximal and distal ends (60, 62) and being releasably retained in a proximal position (Fig. 1) where said proximal end (62) of safety shield (28) is spaced from said distal end (36) of said needle cannula (22);

E) said safety shield (28) being movable upon release, from said proximal position (Fig. 1) to a distal position (Fig. 4) where said safety shield

(28) surrounds said distal end (36) of said needle cannula;

F) a spring (32) for propelling said safety shield (28) from said proximal position (Fig. 1) to said distal position (Fig. 4); wherein

G) said safety shield (28) is slidably disposed between said needle cannula (22) and said substantially tubular housing (80), said distal end (62) of said safety shield (28) being substantially flush with or projecting only slightly from said substantially tubular housing (80) when said safety shield (28) is in said proximal position; and wherein

H) said safety shield (28) completely covers said distal end (36) of said needle cannula (22) when said safety shield (28) is in said distal position;

H') wherein the needle holder(12) has a proximal end (14), a distal end (16) and a tubular sidewall (18) extending between the ends (14, 16);

I) wherein said proximal end (14) of said needle holder (12) comprises means for receiving an evacuated tube,

J) wherein the needle assembly (10) further comprises an actuating means which is triggered by insertion of the evacuated tube into the proximal end of said needle holder (12) to cause the release of said safety shield (28)."

Claims 2 to 5 are dependent claims, with claim 3 reading as follows:

"The needle assembly and needle holder of Claim 2, wherein said coil spring (32) exerts a spring force of 0.088 N to 0.88 N (0.020-.020 pounds) between said safety shield (28) and one of said hub (24) or said

housing (80) while said safety shield is in the proximal position."

VII. The appellant's arguments are essentially those on which the reasons of the present decision are based.

VIII. The respondent's arguments are summarised as follows:

The statement of grounds of appeal was so unclear that the appeal ought to be deemed inadmissible. On page 3 thereof it was stated that the main request corresponded to the main request as filed during the oral proceedings before the Opposition Division whereas feature J) of claim 1 of those requests was clearly different. Therefore, it was unclear what the appellant was pursuing as a main request. In addition the appellant only discussed the compliance of feature J) with Article 84 EPC, but not the question of whether the introduction of feature J) in the claim would be allowable under Article 123(2) EPC. Moreover, the respondent was left with the burden of determining itself why the appellant believed that any of the filed requests met the requirements of the EPC, and in particular of novelty and inventiveness over the cited prior art.

Secondly, the appeal ought to be rejected as inadmissible because it was totally unclear whether any of the requests comprised dependent claims. For the respondent, it had to be clearly set out if dependent claims were included in any request because the appellant might want to use such dependent claims, even late in the proceedings, to save its patent. The respondent was left with the burden having itself to determine whether some of the dependent claims were maintained in the requests. Without knowing the set of

claims which the appellant intended to pursue, it was not possible for the respondent to prepare its defence. Furthermore, claim 1 of each of the auxiliary requests filed with the statement of grounds of appeal was directed to "a shieldable assembly and a needle holder", whereas, assuming that the dependent claims of the patent as granted were maintained in the requests (which was not stated anywhere), they were all directed to a shieldable needle assembly according to claim 1. Moreover, in the opposition brief it had been mentioned that claims 2, 3, 6, 9 and 11 as granted were in contradiction with Article 123(2) EPC.

All of the claim requests submitted with the statement of grounds of appeal were filed late, and were not prima facie allowable. They ought therefore not to be admitted into the proceedings, particularly since claims of the above requests also raised questions of clarity (Article 84 EPC).

The claim requests filed with letter dated 3 November 2014 were submitted even later, without any justification for this lateness. The patentee even requested that the case be sent back to the first instance and was only attempting to prolong the proceedings to hinder the respondent from operating the patent which had been deemed invalid by the first instance.

Feature I) of claim 1 of the first auxiliary request submitted with the statement of grounds of appeal did not comply with Article 123(2) EPC. Paragraph [0005] of the application as filed, indicated as support by the appellant, described the related prior art, not the invention itself. Hence, it did not provide a suitable basis for this amendment. Feature J) likewise did not

comply with Article 123(2) EPC. The cited paragraph [0016] mentioned that "actuating means are provided for releasing a shield from the proximal position, and enabling the biasing means to propel the shield to the distal position". Paragraph [0073] mentioned that "activation of shield 28 is achieved automatically and passively by insertion of blood collection tube 20 into proximal end of needle holder 12". Feature J) did not comply with Article 123(2) EPC because there was no explicit link between the "actuating means for releasing the shield" of paragraph [0016] and "activation of the shield by insertion of blood collection tube" in paragraph [73]. In particular, it was not possible to derive directly and unambiguously from these two paragraphs that the actuating means were triggered by insertion of the evacuated tube as claimed in feature J). Further, paragraph [0073] referred explicitly to a "blood collection tube" and offered no basis for broadening to an "evacuated tube" as claimed.

Reasons for the Decision

1. Admissibility of the appeal

Pursuant to Rule 99(2) EPC the statement of grounds of appeal shall indicate the reasons for setting aside the decision impugned and the facts and evidence on which the appeal is based.

With its statement of grounds of appeal, the appellant requested that the patent be maintained on the basis of a main request or one of four auxiliary requests attached to this statement. The text of claim 1 of this main request is reproduced in part 1 (dealing with this request) of section III (entitled "Art. 123(2) EPC") of

the statement. It is thus clear that this is the main request pursued in the appeal procedure. The fact that it is - erroneously - stated in this part of the statement that this main request corresponds to the main request as filed during the oral proceedings before the Opposition Division and that the basis of feature J) of this latter request is being discussed in this part does not render the request situation unclear, as alleged by the respondent. Also, it is not correct that "the appellant only discusses the compliance of feature J) with Article 84 EPC, but not the question of whether the introduction of feature J) in the claim would be allowable under Article 123(2) EPC": the penultimate paragraph of said part 1 of the statement (page 7) does in fact indicate a basis for this feature in the original application, and the following paragraph states that Article 123(2) EPC is therefore not violated. Accordingly, the objection raised in the impugned decision is addressed and at least one reason is given why the decision is to be set aside. The fact that issues under Article 84 EPC (which are not part of the impugned decision) are also discussed in this part of the statement is of no further relevance. Since the impugned decision does not deal with the requirements of the EPC other than Article 123(2), it is not necessary that the statement of grounds of appeal addresses these issues and deals with novelty and inventive step, as suggested by the respondent, in order for the appeal to be admissible.

The issue that all the requests filed with the statement of grounds of appeal comprised only independent claim 1 (with no dependent claims being recited) is not decisive either for the admissibility of the appeal. In such a situation, the respondent and the Board could assume that the appellant did not wish to pursue

maintenance of the patent with dependent claims being included. With one independent claim comprised in each request, the requirement of admissibility of the appeal is already fulfilled since the facts on which the appeal is based are thus established. The respondent was in a position to present its counter-arguments with regard to these independent claims, and the issue of any further objections that might be raised by the respondent with regard to dependent claims is of no significance with regard to the admissibility of the appeal. The impugned decision did not deal with any of the dependent claims.

Accordingly, the appeal is admissible.

2. Admissibility of requests

The claim requests filed with the statement of grounds of appeal define the appellant's case in the appeal proceedings (Article 12(2) RPBA). They were filed in due time and, contrary to the respondent's view, cannot in principle be considered to be filed late. Also, to be admissible, they do not have to be prima facie allowable, as contended by the respondent.

On the other hand, the claim requests submitted by the appellant with its letter of 10 October 2014 and during the oral proceedings were in fact filed late and thus constitute amendments to the appellant's case, with their admissibility to be considered at the Board's discretion. Pursuant to Article 13(1) RPBA this discretion is to be exercised in view of inter alia the complexity of the new subject matter submitted and the need for procedural economy. In view of the fact that the dependent claims added to each of these requests as compared to the set of requests filed with the

statement of grounds of appeal correspond to dependent claims 10 to 13 of the patent as granted, their subject-matter cannot be seen as unduly augmenting the complexity of the case. The dependent claims were also comprised in the requests underlying the impugned decision. Furthermore, with the impugned decision only dealing with the requirements of Article 123(2) EPC, a remittal to the department of first instance is to be envisaged, irrespective of whether dependent claims are comprised in the requests. Accordingly, their admission is not contrary to the need for procedural economy.

In view of the above, the appellant's claim requests are admitted into the procedure.

3. Amendments

Feature A) of claim 1 of the first auxiliary request filed during the oral proceedings is amended by addition of a needle holder which is unitary or integral with a portion of the needle assembly. This amendment is based on paragraph [0059] of the application as filed. Features B) and F) are comprised in original claim 1. Feature C) is amended in that only **at least a portion** of the substantially tubular housing projects distally from the hub, as disclosed in Figure 19, and in that the feature of the tubular housing being spaced outwardly from the needle cannula has been omitted. This latter feature, however, is still comprised in the claim by virtue of feature G) which defines that the safety shield (telescoped over the needle cannula as required by feature D)) is disposed between the needle cannula and the tubular housing. Features D) and E) and the first part of feature G) are based on original claim 1 in combination with the first

sentence of paragraph [0066] of the application as filed.

Compared to original claim 1, claim 1 of the patent as granted additionally comprises the second part of feature G) and feature H), based on the passage in the last line of page 13 and the first paragraph of page 14 of the description as originally filed.

The basis for feature H') can be found in lines 5 to 6 of paragraph [0057] of the description as filed.

Feature I) is based on lines 1 to 7 of paragraph [0057] of the description as filed (and not on paragraph [0005], as erroneously stated in the statement of grounds of appeal). This passage initially refers to "an evacuated container" and further on to "a blood collection tube 20". The expression "evacuated tube" in feature I) is also used in paragraph [0016] of the application as filed. The skilled person reading the original description would recognise that the term "evacuated tube" may be used in feature I).

Feature J) is based on paragraphs [0016] and [0073] of the application as filed. The respondent's objection that there is no disclosure of the actuating means being **triggered** by insertion of the evacuated tube is not understood: this is exactly what is stated in the penultimate sentence of paragraph [0016].

The above-mentioned sentence refers to triggering **by the movement of the evacuated tube into communication with the proximal end of the needle cannula**. In the Board's view, fluid communication of the evacuated tube with the proximal end of the needle cannula is not a necessary precondition for the triggering of the

actuating means, and it is therefore permissible to omit this feature from the claim without violating the requirements of Article 123(2) EPC. As stated in the third sentence of paragraph [0073] of the application as filed, activation of the shield 28, i.e. its release, is achieved or triggered "automatically and passively by insertion of blood collection 20 tube into the proximal end 14 of needle holder 12". Accordingly, the mere insertion of the tube is already sufficient for achieving the triggering. Fluid communication of the evacuated tube with the proximal end of the needle cannula is a separate and additional effect which is addressed in the following sentence of the paragraph, referring to "[s]ufficient insertion of blood collection tube will cause proximal end 34 of needle cannula 22 to pierce through the elastomeric septum 21 ...". Activation or triggering of the safety shield and establishing fluid communication between the needle cannula and the evacuated tube are two independent functions of the device which are not interrelated with each other. This also becomes evident from the preceding paragraphs [0070] and [0071] of the application as filed where the mechanism of activation of the safety shield is described without any reference to such fluid communication. As can also be seen in the drawings, it is the engagement of the proximal end 78 of the actuator 30 with the evacuated tube, more particularly its septum 21, which is relevant for the releasing of the safety shield, and not the establishment of fluid communication when the septum is subsequently pierced. The respondent has not raised any objection in this regard.

Claims 2 to 5 correspond to original claims 9 to 12, respectively, made dependent from the needle assembly and needle holder according to claim 1. The replacement

of the feature "0.020-.020 pounds" in original claim 10 by "0.088N to 0.88N (0.020-.020 pounds)" in present claim 3 complies with the requirements of Rule 49(10) EPC (incorporating an obvious correction in accordance with Rule 139 EPC of the upper limit value of the range as disclosed in paragraph [0072] of the description as filed) and does not contravene Article 123(2) EPC, as contended by the respondent in its opposition brief.

Accordingly, the Board is satisfied that the subject-matter of claims 1 to 5 of the first auxiliary request filed during the oral proceedings complies with the requirements of Article 123(2) EPC. It is therefore not necessary to deal with the lower-ranking requests.

4. Remittal

Since the impugned decision only deals with Article 123(2) EPC, the Board finds it appropriate to exercise its discretion under Article 111(1) EPC to remit the case to the department of first instance for further prosecution, following the request of the appellant.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance for further prosecution.

The Registrar: The Chairman:

D. Hampe E. Dufrasne

Decision electronically authenticated