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**Datasheet for the decision  
of 21 December 2016**

**Case Number:** T 2117/11 - 3.4.01

**Application Number:** 01274522.0

**Publication Number:** 1377342

**IPC:** A61N5/10, A61M36/00

**Language of the proceedings:** EN

**Title of invention:**  
PRE-LOADED NEEDLE ASSEMBLY

**Applicant:**  
Eckert & Ziegler BEBIG s.a.

**Headword:**

**Relevant legal provisions:**  
RPBA Art. 12(2), 12(4), 13(1)

**Keyword:**  
Statement of grounds of appeal - party's complete case  
Late-filed request - change of subject-matter  
Devolutive effect of the appeal

**Decisions cited:**  
T 1382/08

**Catchword:**



**Beschwerdekammern**  
**Boards of Appeal**  
**Chambres de recours**

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Case Number: T 2117/11 - 3.4.01

**D E C I S I O N**  
**of Technical Board of Appeal 3.4.01**  
**of 21 December 2016**

**Appellant:** Eckert & Ziegler BEBIG s.a.  
(Applicant) Zone Industrielle C  
7180 Seneffe (BE)

**Representative:** Gulde & Partner  
Patent- und Rechtsanwaltskanzlei mbB  
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**Decision under appeal:** Decision of the Examining Division of the  
European Patent Office posted on 25 April 2011  
refusing European patent application No.  
01274522.0 pursuant to Article 97(2) EPC.

**Composition of the Board:**

**Chairman** G. Assi  
**Members:** P. Fontenay  
J. Geschwind

## **Summary of Facts and Submissions**

I. The appeal lies from the decision of the examining division, remitted to the post on 25 April 2011, to refuse European patent application No. 01 274 522.

The decision simply refers to three previous communications dated, respectively, 8 January 2008, 19 March 2009 and 1 October 2010. The decision deals with a set of claims filed on 29 September 2009.

In the first communication dated 8 January 2008, the examining division raised objections of lack of novelty (Article 54(1) EPC), inventive step (Article 56 EPC) and unity (Article 82 EPC). With regard to unity, the examining division held that the claims relating, on the one hand, to a needle assembly and, on the other hand, to a method of making a needle assembly were not linked by the same special technical features in the sense of Rule 30(1) EPC 1973 (Rule 44(1) EPC).

In reply, by letter of 10 July 2008, the applicant filed a new set of amended claims referring to a needle assembly and a method of making a needle assembly.

By letter of 4 September 2008, observations by a third party were filed (Rule 114 EPC).

With the second communication of 19 March 2009, the examining division raised further objections under Articles 123(2), 54(1) and 56 EPC. Moreover, it maintained the objection of lack of unity.

In reply, by letter of 29 September 2009, the applicant filed a new set of further amended claims limited to a needle assembly. As to unity, the applicant indicated

that "*With regard to the objection raised under Article 82 EPC, which the applicant notes is the first objection raised on this application under Article 82 EPC, claims 11 to 14 have been deleted. The applicant reserves the right to file a divisional application to the deleted claims*".

In the third communication of 1 October 2010, sent as annex to a summons to attend oral proceedings, the examining division raised further objections under Articles 123(2), 84, 54(1), (3) EPC. Lack of novelty against claim 1 was based on both document WO-A-00/04953 (D4) and document WO-A-02/34325 (D2).

In reply, by letter of 25 March 2011, the applicant did not submit any further arguments or claims and requested a decision according to the state of the file.

- II. The appellant (applicant) filed the notice of appeal on 23 June 2011. The prescribed appeal fee was paid on the same date. The statement of grounds of appeal was received on 5 September 2011.
  
- III. With the statement of grounds, the appellant requested that the decision under appeal be set aside and a patent be granted on the basis of a new set of claims 1 to 12 directed to a needle assembly, as annexed to the statement of grounds.

As an auxiliary request, the appellant requested to be heard at oral proceedings prior to any adverse decision.

IV. In accordance with the appellant's request, a summons to attend oral proceedings was issued on 14 September 2016.

V. In a communication of the Board pursuant to Article 15(1) RPBA issued on 2 November 2016, the appellant was informed of the provisional opinion of the Board with regard to the request then pending.

In particular, the attention of the appellant was drawn to a contradiction (Article 84 EPC) between the wording of claim 1 and the embodiment of Figure 6c. More fundamentally, attention was drawn to the fact that the alleged effect of a consistent positioning of the plug of the claimed needle assembly, relied upon by the appellant to justify novelty and inventive step of the claimed subject-matter, did not derive from the wording of claim 1. As a consequence, both documents D2 and D4 appeared to constitute particularly relevant items of prior art. Attention was further drawn to document US-A-5 395 319 (D9), cited by the third party in the course of the examination proceedings, which also appeared to disclose relevant prior art.

VI. In response to the preliminary opinion issued by the Board, the appellant filed, with a letter dated 21 November 2016, a new main request consisting of claims 1 to 4 and a correspondingly adapted version of the description. The new request replaced the previous request on file.

The claims of the new main request were directed to a method of making a needle assembly. The claims corresponded to the method claims 17 to 20 as originally filed.

In its letter, the appellant stressed that original claims 17 to 20, regarding a method of making a needle assembly, had indeed been cancelled in response to the second communication issued by the examining division, but that such cancelling had, however, been done without prejudice and solely with the intention to expedite prosecution of the device claims.

- VII. By letter of 19 December 2016, an auxiliary request was filed. It consisted of one single claim directed to a method of making a needle assembly and a correspondingly amended version of the description. The claim corresponded to a combination of original claims 17 and 18.

It was, in particular, observed that neither the International Search Report (ISR) nor the supplementary European Search Report (ESR) had revealed any prior art documents relevant for the issues of novelty and inventive step.

- VIII. Oral proceedings before the Board took place on 21 December 2016 in the presence of the appellant's representative.

The debate during the oral proceedings focused on the issue of the admissibility of the main and auxiliary requests.

The appellant reiterated the view that the claims according to the main request, corresponding to original claims 17 to 20, had been searched and that a positive assessment of their patentability had been made, as resulted from the PCT phase and the supplementary ESR. In the course of the ensuing European phase before the EPO, no objection of lack of

novelty or lack of inventive step had ever been raised by the examining division against said claims.

Moreover, since the claims filed with the statement of grounds of appeal were directed to a needle assembly and the new requests were directed to a method of making such a needle assembly, the criterion of convergence, relied upon by the boards of appeal when deciding on the admissibility of new filed requests, should have been considered to be met under the present circumstances.

Finally, the appellant referred to the length of the appeal procedure and to the financial burden which would have resulted if the appellant had opted for the filing of a divisional application instead of pursuing the matter in the framework of the present application.

IX. Claim 1 of the request filed with the statement of the grounds of appeal reads:

*"1. For implanting a therapeutic elements, a needle assembly comprising a cannula (12) having a wall and a sharpened distal end (18,180), a line of elements (28, 128) in the cannula extending rearward from the distal end, and a stylet (22) receivable in the cannula and having a distal end engaging an end of the line of elements more remote from the distal end of the cannula, characterized in that a frictionally held plug (32, 132, 232, 332) is disposed in the cannula at the distal end thereof, the frictionally held plug engaging portions of the cannula wall to yieldably retain the frictionally held plug within the cannula and including a rearward surface contacting the element most proximate the distal end to position the element most*



*proximate the distal end a predetermined distance from the distal end."*

Claims 2 to 12 of the request filed with the statement of grounds of appeal are dependent claims.

Claim 1 according to the pending main request reads:

*"1. A method of making a needle assembly for implanting therapeutic elements, comprising the steps of:*

- a. providing a cannula having a wall and having a sharpened distal end and providing a generally cylindrical plug,*
- b. placing the plug into the sharpened distal end of the cannula to reside there, and*
- c. modifying the diameter of the plug to enhance its frictional engagement with the wall of the cannula."*

Claims 2 to 4 of the pending main request are dependent claims.

Claims 1 to 4 of the pending main request correspond to original claims 17 to 20.

The pending auxiliary request consists of one single claim which reads:

*"1. A method of making a needle assembly for implanting therapeutic elements, comprising the steps of:*

- a. providing a cannula having a contiguous wall and having a sharpened distal end and providing a generally cylindrical plug,*
- b. placing the plug into the sharpened distal end of the cannula to reside there, and*

*c. modifying the diameter of the plug to enhance its frictional engagement with the contiguous wall of the cannula, wherein the diameter is modified by heating."*

Said claim 1 corresponds to a combination of original claims 17 and 18.

## **Reasons for the Decision**

### *1. Admissibility of the appeal*

The appeal meets the requirements of Articles 106 to 108 EPC and Rule 99 EPC. It is thus admissible.

### *2. Admissibility of the main and auxiliary requests*

2.1 With the statement of grounds, an amended set of claims was filed to replace the set of claims underlying the impugned decision. These amended claims, as well as the claims underlying the impugned decision, were limited to a needle assembly. In the statement of grounds, the appellant took issue with the reasoning of the examining division as it resulted, more specifically, from the communication of 1 October 2010. The appellant, hence, neither filed a request for claims directed to a method, nor commented on the objection of unity which had been raised earlier in the course of the examination proceedings and had eventually led to his opting for claims limited to the needle assembly.

On the other hand, the pending main request, filed by letter of 21 November 2016, and auxiliary request, filed by letter of 19 December 2016, on which the Board has to adjudicate, concern a method of making a needle assembly. In said letters, the appellant did not

contest or even comment the views expressed by the Board in the communication of 2 November 2016 with regard to the request filed with the statement of grounds. Moreover, the appellant did not make any attempt to amend the claims relating to a needle assembly by taking into account the objections and comments of the Board. Instead, the appellant filed two requests both directed to new subject-matter, namely, to a method of making a needle assembly which had been considered by the examining division not to be linked to the needle assembly by a single inventive concept.

2.2 Article 12(2) RPBA specifies, as a general rule, that *"The statement of grounds of appeal ... shall contain a party's complete case"*.

Article 12(4) RPBA further specifies *"the power of the Board to hold inadmissible facts, evidence or requests which could have been presented or were not admitted in the first instance proceedings"*.

Moreover, according to Article 13(1) EPC, *"Any amendment to a party's case after it has filed its grounds of appeal or reply may be admitted and considered at the Board's discretion. The discretion shall be exercised in view of inter alia the complexity of the new subject-matter submitted, the current state of the proceedings and the need for procedural economy."*

It is acknowledged that the applicant would have *de facto* given up the possibility of obtaining a patent on the basis of the product claims, that it actually privileged, if it had filed the present requests concerning a method of making a needle assembly in examination proceedings as a consequence of the objection of lack of unity. In this respect, Article

12(4) RPBA does not constitute a valid basis for not admitting said new requests.

On the other hand, the criterion of procedural economy relied upon in Article 13(1) RPBA would provide a basis for not admitting the new main and auxiliary requests in the appeal proceedings. This is particularly true, considering the various new issues which would have to be addressed for the first time in appeal proceedings. The Board would consequently have no reason to depart from the principle established in Article 12(2) RPBA, according to which the party's case in the grounds of appeal shall be complete.

However, the Board holds that the main obstacle to the admissibility of said requests, in the present case, rather results from the consequences of the devolutive effect associated with the filing of an appeal.

- 2.2.1 In examination proceedings, the examining division held that the request which incorporated claims directed to the needle assembly and claims directed to a method of making a needle assembly was not allowable since it related to a group of inventions that was not linked by a single general inventive concept. If the applicant considered that the objection raised by the examining division was not justified, it then had the possibility to maintain its request with both the product and method claims. In this way, a refusal based *inter alia* on Article 82 EPC could have been challenged before the Board of appeal. However, faced with the objection of lack of unity, the applicant opted for the invention it actually privileged, namely, the set of claims directed to a needle assembly only. By doing so, the applicant's choice entailed that the examination of the application

was limited to the selected subject-matter only, i.e. the claimed needle assembly.

The applicant was aware of the consequences resulting from its choice, since it explicitly indicated, in its letter of 29 September 2009, that it reserved the right to file a divisional application relating to the deleted claims. As a consequence of the applicant's choice, the final decision of the examining division was based on the set of claims filed on 29 September 2009, that is, a set of claims exclusively directed to a needle assembly.

2.2.2 The devolutive effect of the appeal extends only to the part of the impugned decision which is indicated in the statement of grounds for appeal and actually challenged by the appeal (cf. decision T 1382/08, not published, cf. Headnote, 3). This means that only those issues that were considered and decided upon in the decision can later on be challenged in appeal proceedings. Under the present circumstances, the decision to refuse the application is based on the set of claims filed on 29 September 2009, i.e. a set of claims limited to a needle assembly. This subject-matter thus defines the limit to the power of the Board to examine the appeal and, if applicable, to set aside the impugned decision.

2.2.3 It is noted, however, that the decision to refuse the application is a decision according to the "*state of the file*" (see applicant's letter of 25 March 2011) referring to three communications of the examining division instead of containing a complete self-contained reasoning. These communications relate to three different sets of claims filed, respectively, on 8 October 2007, 10 July 2008 and 29 September 2009. It

follows that the first and second sets of claims referred to did not underlie the decision in suit.

It could, however, be argued, in favour of the appellant, that the reference to said three communications created some ambiguity as to the actual content of the impugned decision and that the objection of lack of unity addressed in the communications of 8 January 2008 and 19 March 2009 would, after all, be part of the appealed decision.

However, since the statement of grounds of appeal, which defines the limit to the power of the Board to examine the appeal, did not challenge this issue, the argument would be unfounded. The devolutive effect of the appeal would not allow an extension of the scope of the appeal to this particular aspect (cf. decision T 1382/08).

2.3 The fact that the claims of the present main and auxiliary requests relate to a method of making a needle assembly and that the decision to refuse the application concerned such a needle assembly, does not affect the above findings, contrary to the appellant's view. It is stressed, in this respect, that it is not proved that the claimed method according to the pending main and auxiliary requests would necessarily result in the manufacture of a needle assembly as previously claimed. No convergence can thus be recognised between the pending requests and the request filed with the statement of grounds.

2.4 Last, the financial considerations, as raised by the appellant, regarding the costs for filing a divisional application, do not represent an issue which the Board should take into account.

2.5 In conclusion, the Board does not admit the main and auxiliary requests into the appeal proceedings with the consequence that no requests are pending.

## Order

### For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



R. Schumacher

G. Assi

Decision electronically authenticated