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**Datasheet for the decision  
of 20 February 2014**

**Case Number:** T 2256/12 - 3.3.10

**Application Number:** 09155570.6

**Publication Number:** 2065061

**IPC:** A61L29/08, A61L2/08, A61L29/14

**Language of the proceedings:** EN

**Title of invention:**  
A method for sterilising a medical device having a hydrophilic coating

**Applicant:**  
Coloplast A/S

**Headword:**

**Relevant legal provisions:**  
EPC Art. 76(1), 123(2), 111(1)  
RPBA Art. 13(1)

**Keyword:**  
Late-filed request - admitted (yes)  
Divisional application - added subject-matter (no)  
Remittal to the department of first instance - (yes)  
outstanding issues

**Decisions cited:**  
G 0010/93

**Catchword:**



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Case Number: T 2256/12 - 3.3.10

**D E C I S I O N**  
**of Technical Board of Appeal 3.3.10**  
**of 20 February 2014**

**Appellant:** Coloplast A/S  
(Applicant) Holtedam 1  
3050 Humlebæk (DK)

**Representative:** Coloplast A/S  
Corporate Patents  
Holtedam 1  
3050 Humlebaek (DK)

**Decision under appeal:** **Decision of the Examining Division of the European Patent Office posted on 27 April 2012 refusing European patent application No. 09155570.6 pursuant to Article 97(2) EPC.**

**Composition of the Board:**

**Chairwoman:** C. Komenda  
**Members:** J. Mercey  
F. Blumer

## Summary of Facts and Submissions

I. The present appeal lies from the decision of the Examining Division refusing European patent application No. 09 155 570.6, which is a divisional application of the European patent application No. 08 153 300.2, which is a divisional application of the European patent application No. 02 017 127.8, which is a divisional application of the European patent application No. 99 972 551.8.

II. The Examining Division found that the then pending main and first auxiliary requests, filed as Requests F and G during oral proceedings before the Examining Division, contained subject-matter which extended beyond the content of the application as filed, thus contravening the provisions of Article 123(2) EPC. More particularly, there was no basis in the application as filed for the term "crosslinking inhibitor" in *inter alia* claim 5 of the main request, which was identical to claim 1 of auxiliary request 1, each of said claims reading as follows:

"A method for protecting the hydrophilic coating of a catheter having such coating during sterilisation using radiation comprising the steps of:

- providing a catheter with a hydrophilic coating
- bringing the catheter into contact with an aqueous liquid for wetting the hydrophilic coating comprising a crosslinking inhibitor
- sterilising said catheter using radiation while said catheter is in contact with said liquid."

The second auxiliary request comprising a single independent claim directed to a sterilised set comprising a catheter provided with a hydrophilic

- coating further defined by particular properties was found to lack an inventive step (Article 56 EPC).
- III. With its Grounds of Appeal filed 29 August 2012, the Appellant (Applicant) requested that the decision under appeal be set aside and that the claims of either requests F or G, corresponding to the main and auxiliary request 1 underlying the contested decision, be remitted to the Examining Division for further prosecution.
- IV. In a communication dated 2 December 2013 pursuant to Article 15(1) of the Rules of Procedure of the Boards of Appeal, the Board indicated that it saw *prima facie* no reason for departing from the conclusions of the first instance. The Board also drew attention to further reasons why the claims of the main request and auxiliary request 1 failed to meet the requirements of Article 123(2) EPC and indicated that claim 1 of the main request was unclear (Article 84 EPC) in view of it being a claim to a product, namely a sterilised set, which contained, however, a process feature, namely "said catheter is brought into contact with..."
- V. With letter dated 20 January 2014, the Appellant filed a new main request H comprising five independent claims, and during oral proceedings, which were held on 20 February 2014, it filed two further requests, I and J. The only claim of request J, which became the new main request, reads as follows:
- "1. A method of protecting the hydrophilic coating of a catheter having such coating during sterilisation using radiation, characterised in that the coating is brought into contact with an aqueous solution comprising a

hydrophilic polymer and exposed to the radiation while in contact with the aqueous solution."

- VI. The Appellant argued that the main request J was admissible, since the subject-matter of the claim was closely related to that of claim 5 of the main request and claim 1 of auxiliary request 1 on which the decision under appeal was based and overcame all the objections in said decision, as well as the objections raised by the Board in its communication of 2 December 2013. It submitted that the amendments found support in both the application as filed, as well as in all applications from which the present divisional application was derived, and thus complied with the requirements of Articles 76(1) and 123(2) EPC.
- VII. The Appellant requested that the decision under appeal be set aside and the case be remitted to the department of first instance for further prosecution on the basis of the main request, filed as request J during the oral proceedings before the Board, or, subsidiarily, on the basis of the first auxiliary request, filed as request I during the oral proceedings before the Board, or on the basis of the second auxiliary request, filed as request H with letter dated 20 January 2014, or on the basis of either of the third or the fourth auxiliary requests, filed as Requests F and G during oral proceedings before the Examining Division and referred to in the statement setting out the grounds of appeal.
- VIII. At the end of the oral proceedings, the decision of the Board was announced.

## Reasons for the Decision

1. The appeal is admissible.

### *Main request*

2. *Admissibility of late-filed request*
  - 2.1 Any amendments to a party's case after it has filed its grounds of appeal are admitted at the Board's discretion (Article 13(1) RPBA). In the present case, the main request was filed at a very late stage of the proceedings, namely as request J during oral proceedings before the Board.
  - 2.2 The single claim of this request is based very closely on claim 5 of the main request on which the contested decision was based (said claim being identical to claim 1 of auxiliary request 1 on which the contested decision was based), said requests being the subject of the Appellant's Grounds of Appeal (see point III above). *Vis-à-vis* each of these claims of these previous requests, the present claim has been amended in substance by replacing the feature "crosslinking inhibitor" with "hydrophilic polymer". In addition, it has been reworded.
  - 2.3 This substantial amendment replaces the feature "crosslinking inhibitor", for which the Examining Division could find no basis in the application as filed and resulting in the main and auxiliary request before it being rejected for failing to comply with the requirements of Article 123(2) EPC, with the feature "hydrophilic polymer", which finds a basis on page 18, line 16 of the application as filed. The rewording of the claim *vis-à-vis* the corresponding claim before the

Examining Division, such that the wording is almost identical to that on page 18, lines 14 to 17 of the application as filed, renders the claim more concise (Article 84 EPC). The deletion of all dependent claims, and of all product claims directed to a sterilised set comprising a catheter provided with a hydrophilic coating, have the effect that the additional objections of the Board in its communication dated 2 December 2013 under Articles 84 and 123(2) EPC no longer apply.

2.4 Thus, since the amendments would appear to overcome all the objections in the decision under appeal with respect to a claim to a method of protecting the hydrophilic coating of a catheter having such coating, as well as the additional objections raised by the Board, the Board exercises its discretion to admit the Appellant's main request into the proceedings.

3. *Amendments (Article 76(1) and 123(2) EPC)*

3.1 The present claim is based on embodiment 10 on page 18, lines 14 to 17 of the application as filed, with basis for the catheter being found on page 5, lines 8 to 9 of the application as filed.

3.2 For these reasons, the Board concludes that the subject-matter of the claim does not extend beyond the content of the application as filed such that the requirements of Article 123(2) EPC are satisfied.

3.3 Identical disclosures are to be found in claim 10 together with page 4, lines 25 to 26, of both the great grandparent and grandparent applications as filed, and at page 18, lines 13 to 16, together with page 5, lines 1 to 2, of the parent application as filed, such that the requirements of Article 76(1) EPC are also met.



3.4 Thus, the Board considers that the amendments made by the Appellant remove all the objections regarding added subject-matter on which the decision under appeal was based.

4. *Remittal*

4.1 Having so decided, the Board has not, however, taken a decision on the whole matter. With respect to claims directed to a method of protecting the hydrophilic coating of a catheter having such coating during sterilisation, the decision under appeal dealt exclusively with amendments which contravened the provisions of Article 123(2) EPC, claims to a **method** not having yet been examined with regard to their fulfilment of all other requirements of the EPC in the present examination proceedings. The finding in the contested decision of lack of inventive step was for the subject-matter of then pending auxiliary request 2, which was directed only to a **product**, namely a sterilised set comprising a catheter with a hydrophilic coating *per se*.

4.2 Proceedings before the Boards of Appeal in *ex-parte* cases are primarily concerned with examining the contested decision (see decision G 10/93, OJ EPO 1995, 172, points 4 and 5 of the reasons), fresh issues normally being left to the Examining Division to consider after a referral back, so that the Appellant has the opportunity for these to be considered without loss of an instance.

4.3 Under these circumstances, the examination not having been concluded, the Board considers it appropriate to exercise the power conferred on it by Article 111(1)

EPC, to remit the case to the Examining Division for further prosecution.

## 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 on the basis of the main request, filed as request J during the oral proceedings before the Board.

The Registrar:

The Chairwoman:



C. Rodríguez Rodríguez

C. Komenda

Decision electronically authenticated