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Datasheet for the decision of 3 November 2016

Case Number: T 0908/13 - 3.3.10

Application Number: 06754955.0

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Language of the proceedings: EN

Title of invention:
A METHOD FOR STERILISING A MEDICAL DEVICE HAVING A HYDROPHILIC COATING

Patent Proprietor:
Coloplast A/S

Opponent:
Astra Tech AB

Headword:

Relevant legal provisions:
EPC Art. 56

Keyword:
All requests - inventive step (no) - arbitrary selection from within closest prior art

Decisions cited:

Catchword:

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Case Number: T 0908/13 - 3.3.10

D E C I S I O N
of Technical Board of Appeal 3.3.10
of 3 November 2016

Appellant: (Patent Proprietor)	Coloplast A/S Holtedam 1 3050 Humlebæk (DK)
Representative:	Laudrup, Peter Coloplast A/S, Holtedam 1 3050 Humlebaek (DK)
Appellant: (Opponent)	Astra Tech AB Aminogatan 1 421 31 Mölndal (SE)
Representative:	Awapatent AB P.O. Box 11394 404 28 Göteborg (SE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 13 February 2013 concerning maintenance of the European Patent No. 1888127 in amended form.**

Composition of the Board:

Chairman	P. Gryczka
Members:	J. Mercey
	C. Schmidt

Summary of Facts and Submissions

I. Appellant I (Opponent) and Appellant II (Patent proprietor) lodged appeals against the interlocutory decision of the Opposition Division which found that European patent No. 1 888 127 in amended form met the requirements of the EPC. Claim 1 of the granted patent reads as follows:

"A method for sterilising a medical device having a hydrophilic coating comprising the steps of:
A) providing a medical device having a hydrophilic coating;
B) immersing said medical device in an aqueous liquid;
C) dissolving hydrophilic polymer(s) in said aqueous liquid; and then
D) sterilising the device by applying a sufficient amount of radiation."

II. Notice of Opposition had been filed by Appellant I requesting revocation of the patent as granted in its entirety on the grounds of lack of novelty and inventive step (Article 100(a) EPC). *Inter alia* the following document was submitted in opposition proceedings:

(9) WO-A-00/30696.

III. The Opposition Division found that the subject-matter of claim 1 of the then pending main request, namely the patent as granted, lacked novelty over document (9), that of claim 2 of auxiliary request 1 did not satisfy the requirements of Article 84 EPC. The subject-matter of auxiliary request 2 was found to be both novel and inventive, document (9) being considered to represent the closest prior art, the claimed method being not

obvious as it went against the teaching of said document.

Claim 1 of auxiliary request 2 maintained by the Opposition Division reads as follows:

"A method for sterilising a medical device having a hydrophilic coating comprising the steps of:
A) providing a medical device having a hydrophilic coating;
B) immersing said medical device in an aqueous liquid;
C) adding hydrophilic polymer(s) to the aqueous liquid after the medical device with the hydrophilic coating has been immersed into the aqueous liquid;
D) dissolving said hydrophilic polymer(s) in said aqueous liquid; and then
E) sterilising the device by applying a sufficient amount of radiation."

IV. With letter dated 19 June 2013, Appellant II indicated that its main request was maintenance of the patent as granted, and additionally filed auxiliary requests A and B. With letter dated 22 September 2016, it filed auxiliary requests C and D. During oral proceedings before the Board, held on 3 November 2016, Appellant II declared that its auxiliary request D should be replaced by the request to maintain the patent on the basis of the claims as maintained by the Opposition Division.

Claim 1 of auxiliary request A differs from claim 1 of the main request only in that the word "thereafter" has been added at the end of step B.

Claim 1 of each of auxiliary requests B and C differs from claim 1 of the main request only in that it has been restricted to a method of sterilising a catheter.

V. Appellant II submitted that the subject-matter of all requests was novel over document (9) and inventive. Starting from the disclosure of claim 1 of document (9) as closest prior art, the problem to be solved was essentially the provision of a simplified method of sterilising a medical device having a hydrophilic coating that maintained low friction of the coating when used. Even if the problem were to be regarded as merely the provision of an alternative method, Appellant II agreed with the argumentation of the Opposition Division in the contested decision that adding hydrophilic polymer(s) to the aqueous liquid after immersion of the medical device was going against the teaching of document (9).

VI. Appellant I argued that the subject-matter of claim 1 of the main request and auxiliary requests A to C was not novel over document (9), nor was it inventive, document (9) representing the closest state of the art. Said document disclosed sterilising a coated medical device comprising bringing said device into contact with an aqueous liquid containing a hydrophilic polymer, said method embracing the method of the patent in suit, as the hydrophilic polymer could only be added to the aqueous liquid prior to, or after, immersion of the medical device. Since no unexpected effect had been shown for the latter option, it was merely an arbitrary choice and therefore obvious.

Appellant I had no objections under Articles 123(2) and (3) EPC to the subject-matter of the claims as maintained by the Opposition Division.

VII. Appellant II requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request, namely the patent as granted, or - alternatively - on the basis of any of auxiliary requests A to C, auxiliary requests A and B being filed with letter dated 19 June 2013, auxiliary request C being filed with letter dated 22 September 2016 or - as a further auxiliary request - on the basis of the claims as maintained by the Opposition Division.

Appellant I requested that the decision under appeal be set aside and that the patent be revoked.

VIII. At the end of the oral proceedings, the decision of the Board was announced.

Reasons for the Decision

1. The appeals are admissible.

Claims as maintained by the Opposition Division

2. Amendments and Novelty

Appellant I had no objections under Articles 54, 123(2) and (3) EPC to the subject-matter of the claims as maintained by the Opposition Division, nor does the Board see any reason to question its allowability under these articles of its own motion.

3. Inventive step

3.1 The present invention is directed to a method of sterilising a medical device having a hydrophilic

coating, wherein the coating is protected by adding hydrophilic polymer(s) to the aqueous liquid prior to sterilisation (see paragraph [0017] of the patent in suit).

3.2 Claim 1 as maintained by the Opposition Division is directed to an embodiment of the sterilisation method of granted claim 1, wherein the step of adding hydrophilic polymer(s) to the aqueous liquid after the medical device with the hydrophilic coating has been immersed into the aqueous liquid, has been inserted between the steps of immersing the medical device and dissolving said hydrophilic polymer(s) (see point III above). In case this embodiment lacked inventive step, then the subject-matter of claim 1 of each of the main request and auxiliary request A, which both embrace this embodiment, cannot involve an inventive step either. Thus, the subject-matter of claim 1 as maintained by the Opposition Division is examined first as to inventive step.

3.3 Document (9) (see claim 1) is directed to a method for sterilising a medical device having a hydrophilic coating, comprising the steps of immersing said medical device in an aqueous liquid, said liquid comprising a solution of a hydrophilic polymer, and sterilising the device by applying radiation. Said document teaches that most hydrophilic coatings lose their water retention and that the coefficient of friction increases when the coatings are stored in water for an extended period of time and/or particularly during sterilisation using irradiation or autoclaving (see page 4, lines 6 to 9). The invention underlying document (9) is that the water retention can be increased dramatically and the coefficient of friction can be kept low by adding hydrophilic polymers to the

liquid for wetting a hydrophilic coating and that these compounds also protect these properties during exposure to sterilisation using radiation when wetted with such wetting liquid (see page 5, lines 8 to 20).

3.3.1 Thus, the Board considers, in agreement with the Opposition Division and both Appellants I and II, that the method of claim 1 of document (9) represents the closest state of the art for the subject-matter of the claims as maintained by the Opposition Division and, hence, takes this document as the starting point when assessing inventive step.

3.4 In view of this state of the art, the problem underlying the claims as maintained by the Opposition Division, as formulated by Appellant II, was the provision of a simplified method of sterilising a medical device having a hydrophilic coating that maintained the low friction of the coating.

3.5 As the solution to this problem, claim 1 as maintained by the Opposition Division proposes adding hydrophilic polymer(s) to the aqueous liquid **after** the medical device with the hydrophilic coating has been immersed into the aqueous liquid.

3.5.1 Appellant II submitted that said problem had been solved, since adding the hydrophilic polymer(s) to the aqueous liquid after the coated medical device had been immersed therein, rather than before, allowed the aqueous medium and the hydrophilic polymer(s) to be stored separately and just mixed when needed. This resulted in the level of degradation of the polymer being kept at a minimum, since stirring, heat generation, and oxidation, resulting from storage of the polymer solution, was avoided (see paragraphs

[0024] and [0025] of the patent in suit). Table 3 of the patent in suit showed that the low friction of the coating of the medical device was indeed maintained.

3.5.2 The Board accepts that in view of the results given in Table 3 the properties of the sterilised product remain the same, regardless of whether the hydrophilic polymer(s) is/are added before or after immersion of the coated medical device. However, the Board fails to see how adding the hydrophilic polymer(s) to the aqueous liquid after the coated medical device has been immersed therein, rather than before, leads to a simplification of the sterilisation method, since even when the hydrophilic polymer(s) is/are added before immersion of the medical device, the aqueous medium and the hydrophilic polymer(s) may also be stored separately until they are mixed. Furthermore, when the hydrophilic polymer(s) is/are added before immersion of the coated medical device, there is no need to store the resulting polymer solution prior to immersing the medical device, since the hydrophilic polymer(s) may be added immediately before immersion of the coated device to be sterilised, such that there is no reason why the level of polymer degradation should be higher when the polymer is added just before, rather than just after, immersion of the coated device.

3.5.3 Since in the present case the alleged improvement, namely a simplified method of sterilising a medical device having a hydrophilic coating, is not considered credible, the technical problem as defined in point 3.4 above needs reformulation.

3.6 Thus, in view of the teaching of document (9), the objective problem underlying the invention is merely

the provision of a further method of sterilising a medical device having a hydrophilic coating.

3.7 Finally, it remains to be decided whether or not the proposed solution to the objective problem underlying the patent in suit is obvious in view of the state of the art.

3.7.1 The skilled person is taught by document (9) that the water retention and coefficient of friction of a hydrophilic coating may be protected when stored in water for an extended period of time and/or during exposure to sterilisation using radiation when wetted with an aqueous liquid, by adding hydrophilic polymers to the aqueous liquid for wetting the hydrophilic coating (see point 3.3 above). Document (9) clearly specifies (see, for example, page 8, lines 13 to 14, page 9, lines 7 to 8 and 30 to 31, page 10, lines 11 to 12 and all Examples) that the coated device is sterilised while wetted with the polymer-containing solution, but does not disclose at what stage of the process the hydrophilic polymers are added to, and dissolved in, the aqueous liquid. However, there are only two possibilities in this respect, namely addition before or after the immersion of the coated medical device, both of which are embraced by document (9).

In the absence of a surprising effect associated with adding the hydrophilic polymer(s) to the aqueous liquid after the coated medical device has been immersed into the aqueous liquid, rather than before, said order of addition is merely an arbitrary choice, well within the routine activity of the skilled person faced with the mere problem of providing a further method of sterilising a medical device having a hydrophilic coating, and cannot provide the claimed method with any

inventive ingenuity. For these reasons, the subject-matter of claim 1 is obvious.

3.7.2 Appellant II argued, as did the Opposition Division in the contested decision, that document (9) taught away from adding the hydrophilic polymer(s) to the aqueous liquid after immersion of the coated medical device therein, since this would lead to hydrophilic polymer not cross-linked in the hydrophilic coating dissolving into the aqueous liquid (see page 8, lines 1 to 4), resulting in a loss of water retention capability of the coated device, which was exactly what document (9) aimed to avoid.

However, the Board disagrees with this argumentation. The essential teaching of document (9) is that hydrophilic polymers should be added to the liquid for wetting the coated medical device in order to protect the properties of the hydrophilic coating when stored in the wetting liquid for an extended period of time and/or during sterilisation using radiation when wetted with such wetting liquid (see point 3.7.1 above). The fact that document (9) does not specify whether these polymers are added to the aqueous liquid before or after the coated device is immersed therein, the method of claim 1 of said document embracing both possibilities, suggests to the skilled person that this order of addition is not critical, said document only teaching the importance of adding the polymers prior to the sterilisation step.

3.8 For these reasons, the subject-matter of claim 1 as maintained by the Opposition Division is not allowable for lack of inventive step pursuant to Article 56 EPC.

Main request and auxiliary request A

3.9 Since the method defined in claim 1 as maintained by the Opposition Division is encompassed by claim 1 of the main request and auxiliary request A (see point 3.1 above), these requests share the same fate as the claims maintained by the Opposition Division in that they too are not allowable for lack of inventive step pursuant to Article 56 EPC.

Auxiliary requests B and C

3.10 Claim 1 of each of auxiliary requests B and C differs from claim 1 of the main request only in that it has been restricted to a method of sterilising a catheter.

3.11 However, since the closest prior art document (9) already discloses (see page 4, lines 25 to 26) that the medical device to be sterilised may be a catheter, this amendment does not contribute to inventiveness of the subject-matter of claim 1 of this request *vis-à-vis* this document.

3.12 Therefore, auxiliary requests B and C are also not allowable for lack of inventive step pursuant to Article 56 EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairman:

C. Rodríguez Rodríguez P. Gryczka

Decision electronically authenticated