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# Datasheet for the decision of 16 April 2013

**Case Number:** T 2068/09 - 3.3.10

**Application Number:** 99961760.8

**Publication Number:** 1133321

**IPC:** A61L 2/18, A01N 37/16, A61L 101/22

**Language of the proceedings:** EN

**Title of invention:**
Non-corrosive sterilant composition

**Applicant:**
ECOLAB INC.

**Headword:**
-

**Relevant legal provisions:**
EPC Art. 123(2), 56

**Keyword:**
"Main request and first auxiliary request: Inventive step (no)"
"Second, third, fourth and fifth auxiliary request: amendments allowable (no) - undue generalization"

**Decisions cited:**
-

**Catchword:**
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Beschwerdekammern | Boards of Appeal | Chambres de recours

**Case Number:** T 2068/09 - 3.3.10

# D E C I S I O N
**of the Technical Board of Appeal 3.3.10**
**of 16 April 2013**

**Appellant:** (Applicant)
ECOLAB INC.
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St. Paul, MN 55102-2233 (US)

**Representative:**
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**Decision under appeal:**
**Decision of the Examining Division of the European Patent Office posted 18 May 2009 refusing European patent application No. 99961760.8 pursuant to Article 97(2) EPC.**

**Composition of the Board:**

**Chairman:** P. Gryczka
**Members:** C. Komenda
F. Blumer

## Summary of Facts and Submissions

I. The appeal lies from the decision of the Examining Division posted on 18 May 2009 refusing European patent application No. 99 961 760.8 published with the International publication No. WO 00/30690.

II. The decision under appeal was based on the claims according to the then pending main request and a first to third auxiliary requests submitted on 8 December 2008. Independent claim 1 of the main request read as follows:

"1. A method of sterilizing an article comprising mixing a first and a second solution to form a sterilizing solution comprising an aqueous solution of a peroxy acid, said first solution comprising a carboxylic acid, hydrogen peroxide and water, and said second solution comprising a buffering agent for pH between about 5 and 7, said sterilizing solution comprising at least 100 parts per million of peroxy acid at a pH of 5 to 7, immersing said article in said sterilizing solution for at least 5 minutes to sterilize said article, wherein said sterilizing solution has no organic copper or brass corrosion inhibiting compounds therein and wherein said article comprises a medical article having parts made of at least two materials selected from the group consisting of metals, polymers other than rubbers, and rubbers."

Claim 12 of the main request read as follows:

"12. The method of claim 1, wherein the article is a flexible endoscope."

The wording of claims 1 to 11 of the first auxiliary request was identical to the wording of claims 1 to 11 of the main request. Claim 12 of the main request had been deleted.

The wording of claim 1 of the second auxiliary request was based on the wording of claim 1 of the main request, wherein all references to "an article" were replaced by "a flexible endoscope".

The wording of claim 1 of the third auxiliary request was based on the wording of claim 1 of the main request, wherein all references to "an article" were replaced by "parts of a flexible endoscope".

III. The Examining Division had severe doubts whether the amendments made to claim 12 of the main request and to claim 1 of the second and third auxiliary requests fulfilled the requirements of Article 123(2) EPC. Further, the subject-matter of claim 1 of all requests was regarded as not involving an inventive step in the sense of Article 56 EPC. In its decision the Examining Division relied *inter alia* on document

(1) US-A-5 077 008.

In particular the Examining Division held that document (1), which was regarded as representing the closest state of the art, also disclosed a method for sterilization of a medical equipment containing parts of metal and plastic, such as endoscopes, by means of peracetic acid at close to neutral pH. The claimed method differed therefrom merely in that according to

the application in suit the sterilizing solution has no organic copper or brass corrosion inhibiting compounds therein. If the article to be sterilized does, however, not contain any brass or copper parts, there was no need to incorporate any organic copper or brass corrosion inhibiting compounds into the sterilizing solution. Therefore, the method according to claim 1 of the main request or of any of the first to third auxiliary requests did not involve an inventive step.

IV. Together with its statement of grounds for appeal dated 15 September 2009 the Appellant filed a main request and a first to fifth auxiliary requests. The main request and the first to third auxiliary requests were identical to those requests on which the decision under appeal was based.

The fourth auxiliary request in the version containing the handwritten amendments was based on the wording of claims 1 to 12 of the main request, wherein in claim 1 the article was characterised in that "said article comprises a medical article having parts made of metals and rubbers".

The fifth auxiliary request was based on the wording of claims 1 to 11 of the fourth auxiliary request, wherein in claim 1 all references to an "article" were replaced by "a flexible endoscope".

V. The Appellant argued that the amendment relating to the article being a flexible endoscope or parts thereof did not represent added subject-matter, since from the reference to the various polymeric materials tested in the experimental section of the application and the

indication that the article had to comprise at least two different materials the skilled person would have automatically had in mind that the article was a flexible endoscope. Further, he brought forward that the focus in the closest prior art document (1) was on the inhibition of the corrosion of metals, such as copper or brass, when sterilizing medical instruments made of these metals. There was no indication that the sterilization method disclosed in document (1) could also be applied to medical articles comprising parts made of polymers or rubbers. The skilled person would not have applied this known sterilization method to medical articles comprising polymers or rubbers, since from his common general knowledge he knew that the presence of organic compounds, such as the organic copper or brass corrosion inhibiting compounds, lead to the corrosion of polymers and rubbers. Although the abstract of document (1) mentioned that the medical instruments to be sterilized may include various metals or plastic parts, the skilled person would not have considered the teaching of document (1) for sterilizing materials other than metals, since the whole specification of this document referred exclusively to the sterilization of articles of metal. The skilled person would, therefore, have disregarded the abstract as being in clear contradiction to the rest of the disclosure of this document. Further, document (1) merely concentrated on the corrosion effects, but did not contain any information as to whether the treatment with the peracetic acid solution indeed resulted in a sufficient sterilization of the articles. Since the state of the art did not give any indication how to modify the known sterilizing solutions in order to make them suitable for sterilizing medical articles

comprising parts made of metals, polymers or rubbers without corroding the various materials, the claimed method was based on an inventive step.

VI. The Appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the main request or, subsidiarily, on the basis of any of the first, second, third, fourth and fifth auxiliary requests, all requests as filed with the statement setting out the grounds of appeal dated 15 September 2009.

VII. At the end of the oral proceedings before the Board held on 16 April 2013 the decision of the Board was announced.

## Reasons for the Decision

1. The appeal is admissible.

*Main request and first auxiliary request*

2. In the decision under appeal the Examining Division did not raise any objection under Article 123(2) EPC with regard to claim 1. Since claim 1 of the main request, which is identical to claim 1 of the first auxiliary request, appears to be based on a combination of original claims 1 and 19 the Board is satisfied that for the amendments made to claim 1 the requirements of Article 123(2) EPC are fulfilled.

3. *Novelty (Article 54 EPC)*

Novelty of the claimed subject-matter was not objected to in the decision under appeal. The Board on its own sees no reason to take a different view on the basis of the documents on file.

4. *Inventive step (Article 56 EPC)*

4.1 Claim 1 of the application in suit is directed to a method of sterilizing an article by means of a sterilizing solution comprising a peroxy acid obtained from a carboxylic acid in the presence of hydrogen peroxide. A similar method is disclosed in document (1).

Document (1) discloses a method for sterilizing medical instruments, such as endoscopes, which may comprise various materials, such as metals or plastics (column 2, line 31; column 3, line 28; abstract). The method works on substantially all materials with minimal corrosion (column 2, lines 53 to 55). The sterilizing solution is prepared by first mixing the inhibitors, water and the buffering agent and thereafter adding a solution of peracetic acid in water (column 2, lines 30 to 41; column 3, lines 40 to 46). The sterilization solution contains a buffer to give a pH from 5 to 7 to inhibit steel corrosion (column 3, lines 58 to 61); in the example the pH is 6.4 (column 6, line 6). The concentration of peracetic acid in the sterilization solution is from 50 to 10000 parts per million (column 4, lines 48 to 51).

4.2 Starting from this prior art the technical problem to be solved according to the Appellant was to provide a

method for sterilizing a medical article comprising different materials, without corroding the polymer or rubber materials while providing sufficient sterilization.

4.3 As a solution to this technical problem the application in suit proposes the method according to claim 1, which is characterized in that the sterilizing solution has no organic copper or brass corrosion inhibiting compounds therein and that said article is immersed in said sterilizing solution for at least 5 minutes to sterilize said article.

4.4 Having regard to the examples of the application in suit the Board is satisfied that the problem underlying the invention has been successfully solved.

4.5 When looking for a solution to the technical problem as defined in paragraph 4.3 *supra* the skilled person would learn from document (1) that the sterilization method described therein may be applied for sterilizing medical instruments of substantially all materials, thus also metals, polymers and rubbers (abstract; column 2, lines 53 to 55). Further, if the medical article to be sterilized does not contain any brass or copper parts, he would recognize that there was no need to incorporate any organic copper or brass corrosion inhibiting compounds into the sterilizing solution. In particular, if the medical article contains parts of polymers or rubbers he would have avoided to use organic copper or brass corrosion inhibiting compounds in the sterilizing solution, since, according to the Appellant, he knew from common general knowledge that these organic compounds are detrimental to polymers or

rubbers. For achieving the sterilization of the article the application in suit requires immersing the article for at least 5 minutes into the sterilizing solution, whereas according to document (1) the sterilization of the medical instrument is quickly achieved (column 2, lines 50 to 52). Since it has not been demonstrated in the application in suit that the specific choice of the lower limit of 5 minutes for immersing the article into the sterilization solution is related to any technical effect, this threshold is regarded as being merely an arbitrary selection within the scope of document (1). This selection, therefore, represents merely a routine activity of a skilled person, which cannot contribute to an inventive step.

4.6 According to the Appellant the skilled person would only have considered to apply the sterilization method disclosed in document (1) on medical instruments made of metal, since the description of document (1) was silent on materials other than metals, such as polymers or rubbers. The abstract of document (1), which mentioned that the medical instrument might also contain plastic parts, would have been disregarded as being in clear contradiction to the description of document (1).

However, apart from the reference to other materials in the abstract, document (1) clearly indicates in the description that the method works on substantially all materials with minimal corrosion, thus including materials such as polymers or rubbers (column 2, lines 53 to 55). Therefore, the argument of the Appellant cannot succeed.

The Appellant further argued that the organic copper or brass corrosion inhibiting compounds are typically amine compounds, such as triazoles, which are known to exhibit also anti-microbial properties. Therefore, when leaving out these compounds the skilled person would have expected that the sterilizing solution would no longer be effective for sterilizing of the medical equipment.

However, reading document (1) these organic copper or brass corrosion inhibiting compounds were clearly incorporated into the sterilizing solution for their corrosion inhibiting effect. Therefore, when leaving out these compounds the skilled person would have primarily expected to loose the inhibiting effect on the corrosion of copper or brass, but would not have expected any negative effect on the sterilizing property of the sterilization solution. Therefore, this argument cannot succeed.

Further, the Appellant argued that there is no evidence that the method described in document (1) effects a sterilization of the medical instruments, since no experimental data reflecting the anti-microbial effectiveness were given.

However, document (1) relates to sterilization in general and refers in many passages to the sterilization of medical instruments (column 2, line 30 to 32) and that sterilization of the medical equipment is quickly achieved by the anti-microbial agent (column 2, lines 50 to 52). Therefore, even in the absence of experiments demonstrating the anti-microbial effect, the Board accepts that the application of the

sterilization solution disclosed in document (1) exhibits sufficient anti-microbial activity to yield sterilization of medical instruments. Therefore, this argument must also fail.

4.7 For these reasons, the Board concludes that the method as claimed in claim 1 according to the main request and the first auxiliary request does not involve an inventive step within the meaning of Article 56 EPC.

*Second, third, fourth and fifth auxiliary requests*

5. *Article 123(2) EPC*

The amendments made to the claims according to the second, third, fourth and fifth auxiliary requests concern *inter alia* the characterization of the "article" to be sterilized as "flexible endoscope" or as "parts of a flexible endoscope" in claim 1 of the second, third and fifth auxiliary request and in claim 12 of the fourth auxiliary request (see paragraph II and IV *supra*). In the decision under appeal the Examining Division has already objected to this amendment under Article 123(2) EPC.

The only passage in the application documents referring to a "flexible endoscope" is on page 9, line 14, which relates to the definition of the Test Parameters and which reads:

*"The test was performed on pieces of an Olympus flexible endoscopes using a washer/disinfector to reduce manual variables."*

The test referred to in this passage related to a specific corrosion test executed with a specific sterilization solution. In the claims the specific reference of "pieces of an Olympus flexible endoscope" has been generalized to any flexible endoscope or to parts thereof, and the corrosion tests carried out with peracetic acid have been generalized to a sterilization method by means of any peroxycarboxylic acid. Thus, the claimed generalisation of a sterilization method in combination with any flexible endoscope, or parts thereof, results in subject-matter which cannot be derived clearly and unambiguously from the content of the application as filed.

The Appellant argued that the list of materials tested in the application reflected those materials that were commonly used for flexible endoscopes. Further, a flexible endoscope was one of very few medical instruments that uses various materials, such as metals, polymers and rubbers.

However, even if there are only few medical instruments that comprise various materials, there is no indication in the application as filed that only flexible instruments are to be sterilized with the claimed sterilization method. Further, the list of various materials that were tested in the application only relate to the versatility of the sterilization solution, but do not restrict the applicability of the sterilization solution to a specific medical instrument.

Therefore, the replacement of "an article" by "a flexible endoscope" or "parts of a flexible

endoscope" in claims 1 of the second, third, and fifth auxiliary request and in claim 12 of the fourth auxiliary request extends the claimed subject-matter beyond the disclosure of the application as filed. Thus, these amendments do not comply with the requirements of Article 123(2) EPC with the consequence that the second, third, fourth and fifth auxiliary requests must be refused.

## Order

## For these reasons it is decided that:

The appeal is dismissed.

The Registrar The Chairman

D. Magliano P. Gryczka