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**Datasheet for the decision  
of 28 August 2018**

**Case Number:** T 0814/16 - 3.3.10

**Application Number:** 09776220.7

**Publication Number:** 2303346

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

**Language of the proceedings:** EN

**Title of invention:**

BUFFERED SWELLING MEDIA FOR RADIATION STERILIZED HYDROPHILIC  
COATINGS

**Patent Proprietor:**

Coloplast A/S

**Opponent:**

Dentsply IH AB

**Headword:**

**Relevant legal provisions:**

EPC Art. 100(a), 54(2), 56, 100(b), 123(2), 123(3), 84

**Keyword:**

Novelty - (no) - patent as granted

Auxiliary request A. Sufficiency (yes). Novelty (yes).

Inventive step (yes).

**Decisions cited:**

**Catchword:**



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Case Number: T 0814/16 - 3.3.10

**D E C I S I O N**  
**of Technical Board of Appeal 3.3.10**  
**of 28 August 2018**

**Appellant:** Dentsply IH AB  
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**Decision under appeal:** **Decision of the Opposition Division of the European Patent Office posted on 28 January 2016 rejecting the opposition filed against European patent No. 2303346 pursuant to Article 101(2) EPC.**

**Composition of the Board:**

**Chairman** P. Gryczka  
**Members:** R. Pérez Carlón  
W. Van der Eijk

## Summary of Facts and Submissions

- I. The appellant (opponent) lodged an appeal against the decision of the opposition division to reject the opposition against European patent No. 2 303 346.
- II. Notice of opposition had been filed on the grounds of insufficiency of disclosure (Article 100(b) EPC), and lack of novelty and inventive step (Article 100(a) EPC).
- III. The documents filed during the opposition proceedings include the following:
- D1 US 2006/0240069 A1
  - D2 WO 2006/117372 A1
  - D3 WO 2004/075944 A2
  - D4 WO 00/30696
- IV. Claim 1 of the patent as granted, which is the main request of the respondent (patent proprietor), reads as follows:
- "A sterilised set comprising a medical device comprising a hydrophilic coating in contact with an aqueous liquid comprising:*
- a) a hydrophilic polymer;*
  - b) a separate buffer having at least one pKa value between 2.7 and 5;*
- wherein said set has been sterilised using irradiation while in contact with said liquid."*
- V. The opposition division concluded that the claimed sterilised set was sufficiently disclosed, and that

none of documents D1 to D4 disclosed a medical set comprising a separate buffer, as required by claim 1. With respect to inventive step, document D2 was the closest prior art. The problem underlying the claimed invention was how to increase the stability of wet-stored sterilised sets and the solution, which was characterised by the presence of a buffer, was not obvious having regard to the prior art.

- VI. With the response to the statement setting out the grounds of appeal, the respondent filed auxiliary requests A to F. Claim 1 of auxiliary request A differs from claim 1 of the main request in that feature a) is worded as follows:

*"a) a hydrophilic polymer without buffer capacity around pH 4;"*

- VII. The arguments of the appellant where relevant for the present decision were as follows:

The sterilised set of claim 1 was not novel *inter alia* over those of document D2, which disclosed wet-sterilised medical devices having hydrophilic coatings and a swelling, protecting aqueous medium containing an hydrophilic polymer and sodium citrate. By dissolving citrate in said swelling media, a citrate/citric acid buffer will inevitably be formed. Citric acid has a pKa within that required by claim 1.

The statement of grounds of appeal addressed the objections of the opposition division, so the issue of sufficiency of the patent's disclosure should be examined in appeal. The appellant did not dispute that the patent disclosed one way to carry out the invention, but argued that it failed to provide

indications towards further efficient embodiments.

Document D2 disclosed wet-sterilised medical devices in contact with a swelling, protecting aqueous medium comprising citrate and non-buffering hydrophilic polymers, which rendered the set of claim 1 of auxiliary request A not novel.

Further, document D2 disclosed protecting media containing a combination of hydrophilic polymers. A medical device sterilised in contact with a medium containing PVP and a further polymer without buffering properties rendered the set of claim 1 of auxiliary request A not novel.

During the oral proceedings before the board, the appellant agreed with the opposition division and the respondent that document D2 was the closest prior art. The examples in the patent in suit were limited to the combination of PEG 2000 and citrate/citric acid buffer and could not make credible any alleged effect for every embodiment of claim 1 of auxiliary request A. For this reason, the sole problem credibly solved by the claimed sterilised set was how to provide an alternative to the set disclosed in D2. The solution, which was characterised by a swelling media containing substances known to be suitable for that purpose from D2, was obvious to the skilled person. For these reasons, the claimed sterilised set was not inventive.

VIII. The arguments of the respondent where relevant for the present decision were as follows:

The mere addition of citrate to a swelling solution did not inevitably form a buffer, and claim 1 was for this reason alone novel over the sterilised sets of D2.

Further, citrate could also have been added after sterilisation; for this reason too, the claimed set was novel over that of D2.

The respondent requested that the appellant's arguments on the issue of sufficiency not be examined, as they were a mere repetition of those in the grounds of opposition and failed to address the opposition division's objections.

Regardless of the above, the claimed invention was sufficiently disclosed for it to be carried out by a person skilled in the art. It merely required a wet-sterilised medical device having a hydrophilic coating in a swelling media containing a polymer and a buffer. The skilled person would not find any difficulties in manufacturing such a set.

Claim 1 of auxiliary request A required the simultaneous presence of a buffer and a non-buffering polymer. Even if each of them were disclosed in D2, they were not disclosed in combination, and the set of claim 1 of auxiliary request A was thus novel.

Document D2 was the closest prior art. The problem underlying the claimed invention was how to provide a sterilised, wet-stored medical device which, despite not containing PVP in the swelling medium, had good storage properties. The solution was characterised by a swelling medium containing, at the same time, a non-buffering hydrophilic polymer and a separate buffer. The solution mimicked the properties of PVP and thus credibly solved that problem. As the buffering properties of PVP were not known in the art, such a solution was not obvious. For these reasons, the

claimed sterilised set was inventive.

IX. The final requests of the parties were as follows:

- The appellant requested that the decision under appeal be set aside and that European patent No. 2 303 346 be revoked.
- The respondent requested that the appeal be dismissed and European patent No. 2 303 346 be maintained as granted (main request), or alternatively, maintained in amended form according to one of its auxiliary requests A-F, filed with letter dated 20 October 2016.

X. At the end of the oral proceedings, the decision was announced.

### **Reasons for the Decision**

1. The appeal is admissible.

Main request

2. Novelty

2.1 Claim 1 of the patent in suit is directed to a sterilised set comprising a medical device having a hydrophilic coating in contact with an aqueous liquid. Said liquid contains a hydrophilic polymer and a separate buffer having at least one pKa value between 2.7 and 5. The set is obtainable by sterilisation by irradiation while the medical device is in contact with said liquid.



- 2.2 Document D2 discloses medical devices having hydrophilic coatings, sterilised by irradiation in wetted state (page 1, lines 4-6), whose storage aqueous liquid contains a hydrophilic polymer (page 4, lines 14-18). This was not contested.
- 2.3 It was also not disputed that one of the pKa values of citric acid falls within that required by claim 1.
- 2.4 The parties were divided as to whether or not document D2 disclosed a storage medium comprising a separate buffer, as required by claim 1.
- 2.4.1 On pages 13 and 14, document D2 discloses a list of additional components which could be part of the aqueous storage liquid. The list includes sodium citrate (page 13, line 17).
- 2.4.2 The respondent argued that page 14, lines 4-6, of D2 disclosed that components such as sodium citrate may be added to the aqueous solution of hydrophilic polymer "*at any time during process covered by the present invention*". As citrate could have been added after sterilisation, there was no clear and unambiguous disclosure in D2 of a set sterilised while in contact with an aqueous liquid containing sodium citrate.
- 2.4.3 However, sterilisation is the last step of the production of the medical device of D2. Any additives such as citrate are thus to be incorporated into the storage liquid before wet-sterilisation.

The board thus concludes that document D2 discloses a wet-sterilised set comprising an aqueous solution of sodium citrate.

2.4.4 It was not disputed that a buffer requires the simultaneous presence of a salt and its conjugated acid.

It needs to be examined whether or not the mere presence of sodium citrate in the storage liquid of D2 inevitably provides "a buffer having at least one pKa value between 2.7 and 5", as required by claim 1.

The respondent argues that it was not the case, as a buffer would only be formed by adding both citric acid and citrate to the aqueous solution.

2.4.5 However, example 1 of the patent in suit discloses the following aqueous swelling media comprising 6% PEG 2000 [0043]:

liquid	citric acid	trisodium citrate dihydrate
D	-	3%
E	0.6532%	2%

According to the respondent's argument, only solution E would contain a buffer.

However, Table 1 of the patent in suit shows that solution D, formed by adding sodium citrate, has a buffer capacity comparable to that of solution E (entries starting with D1 and E1, lines 21 to 27).

Thus, the examples of the patent in suit prove that an aqueous swelling medium comprising sodium citrate, such as that of D2, contains a citric acid/citrate buffer.

For these reasons, document D2 discloses all the features of claim 1, with the consequence that the

claimed sterilised set is not novel and the ground of opposition under Article 100(a) EPC precludes the maintenance of the patent as granted.

#### Auxiliary request A

### 3. Amendments

3.1 The appellant did not have any objection with regard to the amendments to auxiliary request A.

3.2 Claim 1 finds a basis in the combination of claims 9, 14 and 15 as originally filed, and also results from the combination of granted claims 1 and 5. Independent claim 7 finds a basis in the combination of original claims 17, 21 and 22, and also results from the combination of granted claims 8 and 11. Dependent claims 2 to 6 and 8 to 11 find a basis in claims 10 to 13, 16, 18 to 20 and 23 as originally filed, respectively. The requirements of Article 123(2) EPC are thus fulfilled.

3.3 The amendments do not extend the scope of protection conferred by the patent as granted and thus fulfil the requirements of Article 123(3) EPC.

### 4. Clarity

The amendments to auxiliary request A result from a combination of claims as granted. Compliance with Article 84 EPC is thus not open for examination (G 3/14, OJ EPO 2015, 102, order).

5. Sufficiency of disclosure

5.1 The respondent requested that the appellant's arguments with respect to sufficiency of disclosure be disregarded, as those in the statements of grounds of appeal were a mere repetition of those in the notice of opposition and failed thus to address the opposition division's reasoning.

5.2 The opposition division concluded that the patent in suit provided at least one way of performing the invention and did not need to contain an example of every possible embodiment falling under the claims.

5.3 The appellant did not question that the patent in suit provided one way to carry out the invention. It argued that it did not provide sufficient information in order to carry out the invention over the whole scope of the claimed subject-matter.

The reasoning in the statement of grounds of appeal thus addresses the arguments of the opposition division that the patent in suit did not need to contain an example of every possible embodiment of the claims, and the ground of appeal under Article 100(b) EPC has to be examined as to its merits by the board.

5.4 Claim 1 is directed to a sterilised set and merely requires a medical device having a hydrophilic coating in contact with an aqueous liquid comprising a hydrophilic polymer and a buffer, which has been sterilised using irradiation while in contact.

Medical devices having hydrophilic coatings are well known in the art (D2, D4), and sets obtained by wet-sterilisation using irradiation whose swelling aqueous

media contains a hydrophilic polymer are also well known (D2, D4). Buffers are commonly used and its preparation and use well established. The skilled person would thus not find any difficulty in obtaining sterilised sets according to claim 1.

- 5.5 The appellant's arguments boil down to arguing that the skilled reader was not taught which of the multiple embodiments envisaged by claim 1 could correspond to a product with good properties.

However, claim 1 does not require the claimed set to have any property further than being sterilised. This argument is thus not convincing.

6. Novelty

- 6.1 Document D2 does not disclose an aqueous liquid having, at the same time, a hydrophilic polymer without buffer capacity around pH 4 (feature a of claim 1) and sodium citrate (feature b), for the following reasons:

- 6.1.1 Sodium citrate is mentioned as a suitable additive within a list extending over pages 13 to 14 of D2.

Document D2 further discloses different hydrophilic polymers on page 9, line 6, to page 10, line 9, some with buffer capacity at the pH defined in claim 1 (PVP, which is the most preferred embodiment of D2) and some without (page 9, lines 6 to 12, PEG, CMC).

However, there is no indication in D2 which would make the combination according to claim 1 available to the skilled reader, since in the claimed invention, two selections from two lists (additives, hydrophilic polymers) are required. Such a combination thus

represents an undisclosed selection over the subject-matter of D2.

- 6.1.2 The appellant also argued that page 10, lines 10-11, of document D2 disclosed that "*in one embodiment the hydrophilic polymers are mixtures of the preferred species stated above*". As D2 disclosed polymers with and without buffer capacity at pH 4, a set having a swelling medium containing a combination of those two types was a set according to claim 1.

However, even though D2 discloses aqueous storage media comprising a combination of hydrophilic polymers, it does not, either implicitly or explicitly, disclose the specific combination of the types of polymers mentioned above. Such a combination thus represents an undisclosed selection over the subject-matter of D2.

- 6.1.3 The appellant had no further objections in the context of novelty of auxiliary request A. Those raised with respect to the main request do not apply to claim 1 of auxiliary request A for the following reasons:

Document D4 is equivalent to D2, and the conclusion on the issue of novelty is necessarily the same for D4 as for D2 for the reasons given above. This was not contested.

Document D1 fails to disclose a sterilisation step, let alone sterilisation by irradiation, as required by claim 1. For this reason alone, the claimed set is novel over D1.

Document D3 fails to disclose the combination of features required by claim 1. Thus, claim 1 of

auxiliary request A is also novel over D3.

6.1.4 The board thus concluded that the sterilised set of claim 1 of auxiliary request A is novel, as required by Article 54(2) EPC.

7. Inventive step

7.1 Closest prior art

The opposition division and the parties at the oral proceedings considered that document D2 was the closest prior art. The board sees no reason to differ.

D2 relates to the problem of protecting a medical device's coating during irradiation (page 4, lines 14-20) and of shelf-life of the sterilised set (page 5, lines 9-15).

The sterilised sets of D2 differ from those of claim 1 in that they do not contain, at the same time, a swelling medium having a hydrophilic polymer without buffer capacity around pH 4 and a separate buffer (see point 6. above).

7.2 Technical problem underlying the invention

The appellant argued that the technical problem underlying the claimed invention was how to provide a sterilised, wet-stored medical device, which despite not containing PVP in the storage medium, has good storage properties.

7.3 Solution

The solution to this technical problem is the claimed

sterilised set comprising a medical device and an aqueous liquid, sterilised while in contact by irradiation, characterised in that it contains, at the same time, a hydrophilic polymer without buffer capacity at around pH 4 and a separate buffer having at least one pKa value between 2.7 and 5.

#### 7.4 Success

7.4.1 The respondent relied on the results obtained in the examples with respect to the combination of PEG 2000 as hydrophilic polymer and citric acid/citrate as buffer to show that the problem formulated above had been credibly solved by the features of claim 1.

7.4.2 The appellant did not dispute these results, but argued that the embodiment tested could not prove that the problem as defined above had been credibly solved over the whole scope of the claimed subject-matter.

7.4.3 However, the patent in suit provides an explanation why any combination of a non-buffering hydrophilic polymer and a separate buffer provides a comparable performance in terms of storage stability to sets containing PVP in the swelling medium.

It is known in the art that wet-sterilisation by irradiation impairs the shelf-life of hydrophilic-coated medical devices, and that the presence of PVP in the swelling medium provides a solution to that problem (see for example D2, page 4, lines 14-20).

According to the patent in suit, sterilisation by irradiation produces acid [0011]. If the pH drops below 3.7, this acid catalyses polymer hydrolysis and thus decreases the shelf-life of the medical device



[0012].

The protecting effect of PVP is linked to its buffering properties [0010], which avoids a drop in pH.

If the hydrophilic polymer lacks buffering capacity (feature a of claim 1), the separate buffer required by feature b allows controlling the acidity of the protecting solution and increases the shelf-life over sets containing polymer alone by mimicking the properties of PVP. This effect would be obtained regardless of the nature of polymer and buffer.

Having regard to this explanation, and taking into account the fact that the appellant has not provided any evidence which could prove the contrary, the board concludes that the problem as mentioned in the previous point has been credibly solved by the sterilised set of claim 1.

7.5 It thus remains to be decided whether or not the proposed solution to the objective problem defined above is obvious from the prior art.

The state of the art opposed to the patent in suit does not disclose that PVP had any buffering capacity, or hints at the importance of pH control in the context of shelf-life of wet-sterilised medical devices. Lacking that knowledge, the skilled person would not have considered combining a buffer and a hydrophilic polymer lacking buffer properties at pH near 4 in order to obtain good storage properties.

For this reason, the claimed subject-matter is inventive, as required by Article 56 EPC.

8. Remittal

The description of the patent as granted contains subject-matter not within the scope of the claims of auxiliary request A (see for example [0032], [0035]) and thus requires amendment (Article 84 EPC). The board decided to make use of its discretion to remit the case to the opposition division for the description to be adapted (Article 111(1) EPC). None of the parties objected to the remittal.

**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 with the order to maintain European patent No. 2 303 346 in amended form on the basis of claims 1-11 of auxiliary request A filed with letter of 20 October 2016 and the description yet to be amended.

The Registrar:

The Chairman:



C. Rodríguez Rodríguez

P. Gryczka

Decision electronically authenticated