

**Internal distribution code:**

- (A)  Publication in OJ  
(B)  To Chairmen and Members  
(C)  To Chairmen  
(D)  No distribution

**Datasheet for the decision  
of 25 August 2009**

**Case Number:** T 1534/06 - 3.3.01

**Application Number:** 00926083.7

**Publication Number:** 1204324

**IPC:** A01N 47/44

**Language of the proceedings:** EN

**Title of invention:**  
System for stabilizing samples

**Applicant:**  
Dorn, Gordon L.

**Opponent:**  
-

**Headword:**  
Method for stabilizing samples/DORN

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

**Relevant legal provisions (EPC 1973):**  
-

**Keyword:**  
"Main Request - added subject-matter - (no)"  
"Main Request - inventive step - (yes)"

**Decisions cited:**  
-

**Catchword:**  
-



Case Number: T 1534/06 - 3.3.01

**D E C I S I O N**  
of the Technical Board of Appeal 3.3.01  
of 25 August 2009

**Appellant:**

Dorn, Gordon L.  
29323 Gimpl Hill Road  
Eugene  
OR 97402-9054 (US)

**Representative:**

Bezzubova, Olga  
UEXKÜLL & STOLBERG  
Patentanwälte  
Thomas-Wimmer-Ring 9  
D-80539 München (DE)

**Decision under appeal:**

Decision of the Examining Division of the  
European Patent Office posted 20 March 2006  
refusing European application No. 00926083.7  
pursuant to Article 97(1) EPC 1973.

**Composition of the Board:**

**Chairman:** C. M. Radke  
**Members:** J.-B. Ousset  
R. T. Menapace

## Summary of Facts and Submissions

- I. The appellant lodged an appeal against the decision of the examining division to refuse the European patent application no. 00 926 083.7.
- II. The decision under appeal was based on claims 1 to 12 of the main request filed with the letter of 7 November 2003, claim 1 reading as follows:
- "1. A method for preserving a sample selected from patient specimens or bodily fluids, which may contain microorganisms, comprising:  
preserving the chemical and physical properties of said sample by mixing said sample with an effective amount of a composition comprising a biguanide and at least one other antimicrobial agent, wherein said composition is cidal to said microorganisms when present in said sample."
- III. In its decision, the examining division was of the opinion that the synergism shown for compositions containing biguanides and another biocide has not been made credible for the whole claimed scope. Since synergism was not predictable, it was also not predictable that other non tested compositions containing a biguanide and a biocide would retain the synergistic effect.
- IV. In its statement setting out the grounds of appeal, the appellant referred to the following documents:
- (1) EP-A-0 231 080  
(2) EP-A-0 628 314

and mainly argued as follows:

- Since the problem to be solved by the present application was to preserve the chemical and physical properties of samples from patient specimens or bodily fluids and since both documents (1) and (2) related to different technical fields (e.g. hand cleansing formulations), neither document (1) nor document(2) addressed the same problem.
- Numerous examples of the application, wherein a different second antimicrobial agent is present (e.g. boric acid, propionates...) showed that the problem has been solved.
- The presence of numerous examples did actually show that the effect was retained on the whole breadth of claim 1.

V. In the provisional and non-binding opinion annexed to the summons to oral proceedings, the board cited *inter alia* the following additional document:

(4) US-A-5,670,160

VI. The appellant, in its letter of 3 July 2009, submitted a new main request. Claims 1 and 6 of this request read as follows:

"1. A method for preserving a sample selected from patient specimens or bodily fluids, which may contain microorganisms, comprising:

preserving the chemical and physical properties of said sample by mixing said sample with an effective amount of a composition comprising a biguanide and at least one other antimicrobial agent, selected from the group consisting of a propionate, an aromatic alcohol, a parahydroxybenzoate ester, boric acid and a boric acid derivative, wherein said composition is cidal to said microorganisms when present in said sample."

"6. The method of Claim 1, wherein said parahydroxybenzoate ester is ethyl parahydroxybenzoate."

Furthermore, the appellant argued as follows:

- From different passages of the description it clearly results that parahydroxybenzoate esters are antimicrobial agents according to the invention.
- The description detailed that the preservative compositions according to the invention contained at least two antimicrobial agents.
- "Chemistat II", which is a preferred composition disclosed in the description, contained ethyl parahydroxybenzoate as an antimicrobial agent.

VII. Oral proceedings before the board took place on 25 August 2009.

VIII. The appellant requested that the decision of the examining division be set aside and a patent be granted on the basis of the eleven claims of the main request

submitted with its letter of 3 July 2009 and the corresponding adapted description submitted during the oral proceedings before the board.

IX. At the end of the oral proceedings, the decision of the board was announced.

### **Reasons for the Decision**

1. The appeal is admissible.

#### *Amendments*

2. Claim 1

2.1 The basis for the formulation as a use-claim is to be found on page 1, lines 5 to 6 and claim 71 of the originally filed description. That the compositions used in claim 1 are made of at least two antimicrobial components is recited on page 12, lines 9 to 10 as well as page 11, lines 25 to 27. The following antimicrobial compositions used in claim 1 are described in the originally filed description:

- a biguanide and a propionate (on page 8, lines 12 to 13)
- a biguanide and an aromatic alcohol (on page 9, lines 16 to 17)
- a biguanide and boric acid or a boric acid derivative (on page 7, lines 9 to 10).

2.1.1 The only point to be decided is whether a composition comprising a biguanide and a parahydroxybenzoate ester

is directly and unambiguously derivable from the description as originally filed. In contrast to this, several passages of the description as well as the claims as originally filed are directed to compositions comprising biguanide, a parahydroxybenzoate ester and also a third antimicrobial agent (see, for example, claims 91 to 94 as originally filed or page 8, lines 16 to 18).

2.1.2 As an embodiment of the present invention, a composition comprising a biguanide and at least another antimicrobial agent comprising a compound that reduces the selective permeability of the cell membrane of the microorganisms is disclosed in the description as originally filed (see page 6, lines 7 to 10). Moreover, on page 13, lines 1 to 4 is given a non-exhaustive list of antimicrobial agents, which reduce the cell membrane permeability, among them parahydroxybenzoate esters.

2.1.3 From the passages of the description cited above, the person skilled in the art would thus directly and unambiguously learn that compositions containing a biguanide and at least a parahydroxybenzoate ester were to be used in the method disclosed.

2.2 Therefore, claim 1 fulfils the requirements of Article 123(2) EPC.

3. Claim 6

3.1 That claim specifies the use of ethyl parahydroxybenzoate in the claimed method.

3.2 The original description disclosed compositions containing a biguanide and at least a parahydroxybenzoate ester (point 2.1.3 above). On page 13, lines 8 to 10 of the original description, ethyl parahydroxybenzoate is explicitly indicated as a suitable parahydroxybenzoate. Moreover, ethyl parahydroxybenzoate is the only parahydroxybenzoate ester used in the examples of Table V on page 23 of the description.

3.3 Hence, claim 6 also fulfils the requirements of Article 123(2) EPC.

#### 4. Other claims

4.1 Claims 2 to 4 find their support in claims 72 to 74 and 77, 78.

Claim 5 is supported by claim 87 as originally filed. Claim 7 is supported by claim 105 as originally filed. Claim 8 is supported by the passage on page 20, lines 13 to 17 of the description as originally filed. Claim 9 is supported by the passage on page 35, lines 4 to 7 of the description as originally filed. Claim 10 is supported by the passage on page 13, lines 26 to 30 of the description as originally filed. Claim 11 is based on page 38, lines 10 to 13.

4.2 It follows that the present set of claims is in conformity with the requirements of Article 123(2) EPC.

#### 5. Inventive step

5.1 Document (4) represents the closest prior art, since it is the only document cited in the search report, which



relates to a method for preserving aqueous compositions. Furthermore, the preservative compositions disclosed in this document contain the same constituents as the ones mentioned in the method of the application in suit (see (4), claim 7, points b) and c).

- 5.2 However, this document does not mention a method for preserving patient specimens or bodily fluids. Thus, the problem underlying the present application is to be seen in the provision of a method to achieve a cidal effect against microorganisms while maintaining the chemical and physical integrity of patient specimens or bodily fluids (see page 5, lines 5 to 6 of the application as filed).

The method of claim 1 represents the solution proposed by the appellant to this problem.

- 5.3 Tables VI and VII of the description show that a composition according to claim 1 (e.g. mixture of ethyl parahydroxybenzoate, chlorhexidine and sodium propionate) preserves (stabilizes) an urine sample without added glucose through 24 hours (except a slight pH variation) and an urine sample with added glucose through 7 days (except a slight variation of pH) when compared to samples of urine not containing the said composition. In view thereof, the board is satisfied that the problem underlying the application in suit has been successfully solved.

- 5.4 Although document (4) discloses methods for preserving an aqueous product by using the same antimicrobial compositions as those used in the present application (see claim 7 and column 1, lines 31 to 37), the person

skilled in the art would not infer from said document the method claimed in the current application. Document (4) does not mention that the preservatives claimed therein are to be applied to patient specimens or bodily fluids rather these preservatives are applied to cosmetic products and formulations for topical administration from the pharmaceutical sector (column 2, lines 29 to 35). Furthermore, none of the other documents cited in the search report relates to the preservation of patient specimens or bodily fluids, so that the person skilled in the art would not find any hint in the prior art to arrive at the claimed method without inventive skill.

Since claims 2 to 11 are all dependent of claim 1, they are also considered as non obvious for the person skilled in the art.

- 5.5 An inventive step is thus acknowledged for the subject-matter of the present claims (Article 56 EPC).

**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 grant a patent with the claims 1-11 filed on 3 July 2009 and the adapted description filed during the oral proceedings before the board.

The Registrar

The Chairman

P. Cremona

C. M. Radke