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File Number: T 458/90 - 3.3.1  
Application No.: 85 904 785.4  
Publication No.: WO 86/02090  
Title of invention: Antiseptic cleansing compositions

Classification: C11D 3/48

DECISION  
of 28 April 1992

Applicant: GLUCK, Bruno Anthony

Headword: Antiseptic compositions/GLUCK

EPC Articles 123(2), 56; Rule 88

Keyword: "Amendment of claims" - "Correction of error" - "Inventive step  
(confirmed for second auxiliary request)"

Catchwords



Case Number : T 458/90 - 3.3.1

**D E C I S I O N**  
of the Technical Board of Appeal 3.3.1  
of 28 April 1992

**Appellant :** GLUCK, Bruno Anthony  
20 King Avenue  
Balgowlah, NSW 2093  
Australia

**Representative :** Wilkinson, Stephen John  
Stevens, Hewlett & Perkins  
1 St. Augustine's Place  
Bristol BS1 4UD (GB)

**Decision under appeal :** Decision of Examining Division of the European  
Patent Office dated 23 January 1990 refusing  
European patent application No. 85 904 785.4  
pursuant to Article 97(1) EPC.

**Composition of the Board :**

**Chairman :** R. Spangenberg  
**Members :** J.M. Jonk  
J-C. Saisset

## Summary of Facts and Submissions

- I. European patent application 85 904 785.4, filed on 24 September 1985 as international patent application No. PCT/AU85/00238 and published as WO 86/02090, was refused by a decision of the Examining Division of 23 January 1990. The decision was based on Claims 1 to 10 submitted on 14 July 1989. The only independent claim read as follows:

"An antibacterial composition comprising a water-soluble salt of chlorhexidine, a nonionic surfactant and an inert diluent or carrier characterised in that the nonionic surfactant is at least one compound having the general formula  $RO-(CH_2CH_2O)_n-H$  wherein RO is the residue of an alkylphenol having only one alkyl radical attached to the aromatic ring or a fatty alcohol and n is a number sufficiently high to assure water solubility between ambient temperatures and 45°C, wherein the chlorhexidine salt is selected from the gluconate, isethionate, formate, acetate, glutamate, succinamate, monodiglycollate, dimethanesulfonate, lactate, diisobutyrate and the glucoheptonate salt said chlorhexidine salt being present at a concentration of from 0.1 to 10.0% w/v and the nonionic surfactant being present at a concentration of not greater than 25% w/v and wherein the weight ratio of the chlorhexidine salt to nonionic surfactant is not greater than 1:7, with the proviso that the composition does not contain a polyoxyethylene-polyoxypropylene condensate or an amphoteric surfactant."

- II. The Examining Division held that the upper limits in Claim 1 for the chlorhexidine salt and the nonionic surfactant of 10% w/v and 25% w/v respectively were not compatible because of the condition that the ratio of the

chlorhexidine salt to the surfactant must not be greater than 1:7.

The Applicant's interpretation of the claim that the ratio of the chlorhexidine salt to the surfactant must be 1 : not greater than 7 would not comply with the meaning that any skilled person would give to said condition.

Moreover, if the Applicant's interpretation of this ratio were to be accepted, the subject-matter of Claim 1 would not involve an inventive step, because a ratio of the chlorhexidine salt to the nonionic surfactant of 1 : not greater than 7 was well known from the state of the art as follows from

(1) US-A-4 456 543,

which discloses ratios of from 1:2.5 to 1:7, and also from the following documents:

(2) US-A-4 420 484,

(3) DE-A-2 805 248,

(4) AU-B-42 746/72, and

(5) EP-A-0 136 231.

Therefore, as set out in the communications of 16 August 1988 and 10 March 1989, it would have been obvious to the skilled person to modify the compositions disclosed in

(6) US-A-2 830 006,

containing chlorhexidine dihydrochloride and a nonionic surfactant such as an alkylphenol or fatty alcohol polyglycol ether by replacing the chlorhexidine dihydrochloride by the more water-soluble chlorhexidine

digluconate, using a nonionic surfactant of the same type and selecting the desired concentrations.

III. A Notice of Appeal was submitted on 23 March 1990 and the appeal fee was paid on the same date.

A Statement of Grounds of Appeal was submitted on 25 May 1990.

IV. The Appellant argued that the skilled person, in the light of the whole disclosure of the present patent application, particularly the introduction to the specification and the preferred embodiments indicated in the Examples and Claim 4, would understand the disputed condition to mean "1 : not greater than 7". From the introduction to the specification it was clear that one of the aims of the present invention, namely, to enable the use of low concentrations of chlorhexidine salt whilst avoiding deactivation by the nonionic surfactant, could not be achieved by the use of a large excess of the surfactant. Moreover, the skilled person would know that the eight examples originally filed, disclosing weight ratios of from 1:1.5 to 1:3.33, and Claim 4, claiming a concentration of the chlorhexidine salt of 4.0% w/v, would not have been incorporated into the patent specification if the Applicant intended the words "not greater than 1:7" to mean "1 : not less than 7".

In this connection, it was observed by the Appellant that also the Examiner interpreted the disputed ratio in his communications of 9 September 1987 and 16 August 1988 as meaning 1 : not more than 7.

Regarding inventive step, it was pointed out that the cited prior art did not suggest that the technical problem underlying the present patent application, i.e. the

provision of an antibacterial composition containing lower amounts of chlorhexidine and nonionic surfactant in order to reduce the risks of adverse effects on the skin of the users, could be solved by selecting the ingredients and by controlling their concentrations as defined in Claim 1. In this connection, the Appellant referred to

(7) Manufacturing Chemist and Aerosol News,  
October 1973, pages 29, 32 and 33,

which disclosed that from the examined nonionic surfactants Pluronic F87 was the most suitable one, but that a concentration of 4% w/v of chlorhexidine was necessary in admixture with 25% w/v of this surfactant to overcome inactivation and give the desired level of activity.

- V. In the course of the oral proceedings held on 28 April 1992 the Appellant submitted three sets of claims as main, first auxiliary and second auxiliary request, respectively.

Claim 1 according to the main request essentially differed from that underlying the decision under appeal in that "not greater than 1:7" was replaced by "such that for one part by weight of the chlorhexidine salt there are no more than 7 parts by weight of the nonionic surfactant".

The wording of Claim 1 of the first auxiliary request was identical with that of the present main request except that "10.0%" was replaced by "4.0%" and "25%" was amended to "10%".

Claim 1 of the second auxiliary request was identical with that of the first auxiliary request except that the words "at least" (line 4/5), "or a fatty alcohol" (line 8), and

"with the proviso that ... or an amphoteric surfactant"  
(last three lines) were deleted.

In order to support the required inventive step  
comparative tests were submitted.

VI. The Appellant requested that the decision under appeal be  
set aside and that a patent be granted on the basis of the  
main or one of the auxiliary requests submitted during  
oral proceedings.

VII. At the conclusion of the oral proceedings, the Board's  
decision to grant a patent on the basis of the second  
auxiliary request was announced.

#### Reasons for the Decision

1. The appeal complies with Articles 106 to 108 and Rule 64  
EPC and is, therefore, admissible.

2. Main request

2.1 The first issue to be dealt with is whether the correction  
in Claim 1, namely the replacement of the condition that  
the ratio of the chlorhexidine salt to the nonionic  
surfactant must not be greater than 1:7 by the condition  
that for one part by weight of the chlorhexidine salt  
there are no more than 7 parts by weight of the nonionic  
surfactant, meets the requirements of Rule 88 EPC.

2.1.1 In the Board's judgment, the skilled person in reading the  
Claim 1 which was rejected by the Examining Division,  
would immediately note that the claim contains an error  
because the ratio of the chlorhexidine salt to the  
nonionic surfactant being not greater than 1:7 does not

comply with the upper limits for the chlorhexidine salt and the surfactant. In the light of the description of the patent application as originally filed, he would then easily find that the error must concern the claimed ratio because the Examples of the patent application as originally filed disclose ratios of from 1:1.5 to 1:3.33. Moreover, since it is clearly disclosed in the present patent application that a preferred concentration of the chlorhexidine salt is 4% w/v (cf. original Claim 6), the preferred concentration of the nonionic surfactant does not exceed 25% w/v (cf. original Claim 2 and page 3, lines 12 and 13 of the description) and that it is desired to reduce the amount of the nonionic surfactant (cf. page 1, lines 36 to 39, and page 2, lines 11 to 17), in the Board's judgment, the skilled person would immediately conclude that the weight ratio of the chlorhexidine salt to the surfactant must be 4 to not more than 25, i.e. 1 to not more than about 7. This view is strongly confirmed by the fact that the first steps of the examining proceedings were based on just this interpretation of the expression in dispute.

- 2.1.2 It is true that another preferred concentration of the chlorhexidine salt indicated in the present patent application is 2% w/v (cf. original Claim 5) and that this value, in combination with high concentrations of the surfactant up to 25% w/v, might give weight ratios of from 1 to more than 7. However, since it was well known as indicated in the description (cf. page 1, lines 36 to 38, and page 2, lines 8 to 14) that at higher concentrations of nonionic surfactants also higher concentrations of chlorhexidine were necessary to compensate the deactivating effect of the surfactants, in the Board's opinion, the skilled person would not correlate this low chlorhexidine concentration with higher concentrations of the surfactants.

2.1.3 Therefore, the proposed correction in Claim 1 meets the requirements of Rule 88 EPC, because it is immediately evident that nothing else would have been intended than what has been offered as the correction.

2.2 However, as set out below, the Board has reached the conclusion that the subject-matter of present Claim 1 does not involve an inventive step.

2.2.1 According to the description of the present patent application, skin cleansing compositions containing a water soluble salt of chlorhexidine and a nonionic surfactant, namely a polyoxyethylene-polyoxypropylene block copolymer, were known from document (4) (cf. page 1, line 39 to page 2, line 14). With respect to this state of the art, it is stated in the description that the polyoxyethylene-polyoxypropylene block copolymers are low-foaming nonionic surfactants, so that amounts of 20 to 25% w/v were necessary to give sufficient sudsing, even when a foam booster such as an alkyl amine oxide is incorporated in the composition (cf. page 2, lines 2 to 7). Moreover, it is stated, that the compositions exemplified in document (4) contain 4% w/v chlorhexidine, which is well above the amount which normally would be required for skin disinfection, because at the high concentrations of nonionic surfactants, considerable deactivation takes place leaving only a small amount of the chlorhexidine available for antibacterial activity (cf. page 2, lines 8 to 14).

2.2.2 The Board can accept that document (4) represents the closest state of the art. It is true, that document (1) which also relates to antibacterial cleansing products incorporating a soluble salt of chlorhexidine and a nonionic surfactant refers to US-A-3 855 140 and US-A-3 960 745 (which belong to the same patent family as

document (4)) as prior art, but the Board is satisfied that there is no indication that the compositions of document (1), containing nonionic surfactants of the same type of block copolymers as those of document (4), have improved properties.

2.2.3 With respect to the state of the art of document (4) the Appellant contended that it was desirable to reduce the amounts of chlorhexidine salt and nonionic surfactant in order to reduce the risk of skin irritation and the costs of the compositions (cf. also page 2, lines 15 to 25 of the present patent application).

However, since the present Claim 1 is not limited to such desirable lower amounts of these two components, the above improvements cannot form the basis for determining the technical problem which is solved by the claimed subject-matter, because it is immediately apparent from the above statement in the description, which has been affirmed during oral proceedings, that they are not achieved by all compositions comprised by that claim.

The Appellant has further argued during the oral proceedings that the claimed compositions show an improved antibactericidal activity, as can be seen from the results of comparative tests.

In these comparative tests a composition containing 2% w/v of chlorhexidine gluconate and 6% w/v of an ethoxylated nonylphenol was compared with a commercially available composition containing 4% w/v chlorhexidine digluconate and 25% w/v of a Pluronic-type surfactant known from document (4). Thus, the comparison was not made with a claimed composition which is closest to the state of the art, i.e. one containing 4% w/v of chlorhexidine gluconate

and 25% w/v of ethoxylated nonylphenol. Therefore, these tests do not demonstrate that the increase of activity is caused by the presence of ethoxylated nonylphenol, and not simply by the reduced amount of deactivating nonionic surfactant.

Moreover, there is no experimental evidence, either in the present patent application or in the comparative tests as filed, that claimed compositions containing a fatty alcohol polyglycol ether show the alleged improved antibacterial activity. In this connection it is observed by the Board that no conclusions can be drawn from the showed effects of the claimed alkylphenol polyglycol ethers, because it is common general knowledge that the inactivation of the chlorhexidine component by the nonionic surfactant depends on the molecular structure of the surfactant (cf. for instance, document (7), page 29, right column, line 11 of the third paragraph to line 12 of the fourth paragraph) and that the structure of aromatic alkylphenol polyglycol ethers is quite different from that of aliphatic fatty alcohol polyglycol ethers.

Consequently, the advantages referred to by the Appellant cannot be taken into consideration in respect of the determination of the problem underlying the subject-matter of the present Claim 1.

2.2.4 However, in the light of the closest state of the art, this technical problem can be seen in providing a further sufficiently active antibactericidal composition on the basis of a chlorhexidine salt and a nonionic surfactant.

According to Claim 1 this technical problem is solved by compositions containing at least one of the defined nonionic surfactants.

In view of the statements in the present patent application as filed (cf. page 3, lines 6 to 11, and page 4, lines 4 to 12), the Examples and the comparative tests as filed, the Board is satisfied that the above technical problem is credibly solved.

- 2.2.5 However, a suggestion how to solve the present technical problem was already given in document (1), which describes in column 1, lines 35 to 48, that it was known that many nonionic surfactants substantially reduce the antibacterial activity of chlorhexidine, but that with certain nonionic surfactants, such as those disclosed in document (6), the chlorhexidine retains a substantial amount of antibacterial activity (cf. column 1, lines 35 to 48). The nonionic surfactants mentioned in the cited prior art document (6) are, for instance, condensation products of ethylene oxide with alkylphenols or fatty alcohols (cf. document (6), lines 36 to 40).

In the Board's judgment, it was therefore obvious to solve the above-defined technical problem by the choice of a nonionic surfactant selected from alkylphenol or fatty alcohol polyglycol ethers.

3. First auxiliary request

- 3.1 Claim 1 according to this request only differs from Claim 1 of the main request in that the concentration of the chlorhexidine salt is restricted to an amount of from 0.1 to 4.0% w/v and in that the concentration of the nonionic surfactant is not greater than 10% w/v.

- 3.2 The Appellant argued that the requirement of Article 123(2) EPC was met because the upper limit of the concentration of the nonionic surfactant of 10% w/v is

based on the Examples and on the statement on page 3, lines 12 to 15, of the patent application as filed.

- 3.2.1 However, the Board is unable to agree with this submission, because on page 3 it is only stated that when the surfactant is a polyoxyethylene-polyoxypropylene condensate, its content in the compositions does not exceed 10% w/v. Thus, the upper limit of 10% w/v is only related to nonionic surfactants of the type of polyoxyethylene-polyoxypropylene condensates.

Therefore, this statement and the Examples 5 to 8 which are related to compositions containing the same type of nonionic surfactants cannot form a basis for the now claimed concentration of different types of nonionic surfactants, namely alkylphenol or fatty alcohol polyglycol ethers.

In addition, Examples 1 to 4 of the patent application as originally filed disclose compositions containing the nonionic surfactant nonylphenol ethoxylate (i.e. an alkylphenol polyglycol ether) in concentrations of 6% w/v (Examples 1 and 3) and 10% w/v (Examples 2 and 4). The question is now whether the claimed upper limit of the surfactant concentration of 10% w/v can be based on these examples for the two different types of surfactants. In the Board's judgment, this would only be allowable pursuant to Article 123(2) if the skilled person, in the light of the present patent application or common general knowledge, would have readily recognised that both types of nonionic surfactants would have been applied in essentially the same concentrations. However, the Appellant did not provide evidence making it credible that this condition is met. On the contrary, from the disclosure of the present patent application that, when the surfactant is a polyoxyethylene-polyoxypropylene

condensate, its content does not exceed 10% w/v (cf. page 3, lines 12 to 15) and from general technical literature, namely document (7), which discloses that the compatibility of the bactericidal chlorhexidine with nonionic surfactants depends on their chlorhexidine binding properties, it can be concluded by the skilled person that the concentration of the nonionic surfactants normally depends on their structure.

3.2.2 Under these circumstances, in the Board's judgment, the subject-matter of Claim 1 of the first auxiliary request does not meet the requirements of Article 123(2) EPC.

4. Second auxiliary request

4.1 Claim 1 of this request essentially differs from that of the first auxiliary request by the deletion of the nonionic surfactants of the type of fatty alcohol polyglycol ethers.

4.2 The present Claim 1 does not give rise to objections under Article 123(2). The concentration of 10% w/v for the alkylphenol ethoxylates can be based on Examples 2 and 4 of the patent application as filed, because there is no reason why the skilled person would not immediately apply the concentrations given in these examples for ethoxylated nonylphenol to ethoxylated alkylphenols in general. The other amendments, which are essentially based on original Claims 1, 2, 3 and 8, are also acceptable.

4.3 After examination of the cited documents, the Board has reached the conclusion that the claimed subject-matter is novel. Since novelty is not in dispute, it is not necessary to give detailed reasons for this finding.

4.4 The remaining issue to be decided is whether the subject-matter of the present Claim 1 involves an inventive step.

4.4.1 The closest state of the art is, again, considered to be disclosed in document (4) (see section 2.2.2 above), although document (1), e.g. in Examples IV and V, describes compositions which contain 4% w/v chlorhexidine and 10% w/v of a nonionic surfactant. However, these compositions contain, in addition, 1% w/v of an amphoteric surfactant, namely laurylbetaine, and it can be derived from the disclosure of document (1), in particular from the statement in column 6, lines 21 to 31, in context with column 7, line 25 to column 8, line 2, that the presence of the amphoteric surfactant is necessary in the compositions of these examples because of their low nonionic surfactant concentration. Therefore, since it is indicated in the description of the present patent application (cf. page 1, lines 33 to 36), that the presence of an amphoteric surfactant is undesirable because of its skin irritating effect, the disclosure in this document is, in the Board's judgment, not closer to the claimed compositions than that of document (4). As indicated above, document (4) describes antibacterial cleansing compositions containing a soluble salt of chlorhexidine and a nonionic surfactant, namely, a polyoxyethylene-polyoxypropylene block copolymer (cf. Claim 1 and page 3, line 3 to page 5, line 6). Preferred compositions contain from 0.5 to 5.0% w/v of chlorhexidine gluconate and from 10 to 30% w/v, ideally about 25% w/v, of "Pluronic" F87 (cf. page 5, lines 1 to 9).

4.4.2 With respect to this prior art it has been stated by the Appellant - as set out above - that a minimum amount of 4% w/v of chlorhexidine and a minimum amount of about 25% w/v of the most preferred nonionic surfactant, namely, "Pluronic" F87, was necessary to give sufficient sudsing

and sufficient available chlorhexidine for the desired antibacterial effectiveness. This statement is accepted by the Board because it is further supported not only by the examples of document (1), but also by the disclosure of document (7). This document describes that, after a number of tests with different surfactants, "Pluronic" F87 was the least irritant, the most soluble in water and at 25% concentration had suitable viscosity and washing properties (cf. page 29, third paragraph of the chapter headed "Chlorhexidine/Detergent Formulations" and that microbiological tests confirmed that "Pluronic" F87 showed least inactivation of chlorhexidine but that 4% w/v was necessary in admixture with 25% w/v of the nonionic surfactant to overcome inactivation and give the desired level of activity (cf. page 32, the third paragraph of the left column).

- 4.4.3 The Appellant has further argued that high concentrations of nonionic surfactant, such as 25% w/v, considerably deactivate chlorhexidine leaving only a small amount of the chlorhexidine available for antibacterial activity, and also have an adverse effect on the skin (cf. also page 2, lines 8 to 17 of the present patent application).
- 4.4.4 The technical problem underlying the subject-matter of present Claim 1 can, therefore be seen in providing an antibacterial composition based on chlorhexidine and a nonionic surfactant, which shows less deactivation of the chlorhexidine and less adverse effect on the skin.
- 4.4.5 According to present Claim 1, this problem is solved by compositions comprising chlorhexidine and an alkyl phenol ethoxylate (alkylphenol polyglycol ether) having only one alkyl radical attached to the aromatic ring in an amount of at most 10% w/v.

In view of the Examples 1 to 4 and the test results submitted during the oral proceedings, the Board is satisfied that this technical problem is credibly solved, although the comparison was not made with a claimed composition which is closest to the state of the art, i.e. a composition containing 4% w/v of chlorhexidine gluconate and 10% w/v of ethoxylated nonylphenol, since the Board is satisfied that the somewhat lower amount of the surfactant (7% w/v instead of 10% w/v) in the claimed compositions is compensated by the lower amount of chlorhexidine gluconate (2% w/v instead of 4% w/v).

- 4.4.6 In the Board's judgment, the proposed solution is inventive, because the cited prior art documents do not give any suggestion to the skilled person how the above-defined technical problem can be solved.
- 4.4.7 The only cited document which concerns compositions comprising a chlorhexidine salt and an ethoxylated alkylphenol surfactant is document (6). This document discloses an improved process for the manufacture of bactericidal compositions comprising the preparation of a chlorhexidine salt in the presence of a nonionic surfactant (cf. column 1, lines 46 to 66, Claim 1 and Example 1). As nonionic surfactants can be used, for example, condensation products of ethylene oxide with, for instance, alkylphenols, long-chain fatty alcohols and long-chain fatty acids or their amides (cf. column 2, lines 36 to 40). Although the condensation products of ethylene oxide with alkylphenols are indicated as suitable surfactants, the most preferred surfactant is apparently the condensation product of octyl cresol with 9.5 molecular proportions of ethylene oxide (cf. all the examples and Claim 3), which falls outside the now claimed group of surfactants containing only one alkyl radical attached to the aromatic ring. Thus, document (6) does not

give any information about the antibacterial activity obtainable with a particular nonionic surfactant, let alone with a particular amount thereof. Therefore, the information contained in this document could not help the person skilled in the art in solving the present technical problem.

- 4.4.8 Since the subject-matter of Claim 1 involves an inventive step, Claims 2 to 10, which relate to preferred embodiments of the compositions according to Claim 1, are likewise allowable.

Order

For these reasons, it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the Examining Division with the order to grant a patent on the basis of the second auxiliary request submitted during the oral proceedings and of a description yet to be adapted.

The Registrar:



The Chairman:



R. Spangenberg