BESCHWERDEKAMMERN	BOARDS OF APPEAL OF	CHAMBRES DE RECOURS
DES EUROPÄISCHEN	THE EUROPEAN PATENT	DE L'OFFICE EUROPEEN
PATENTAMTS	OFFICE	DES BREVETS

Internal distribution code:

(A) [] Publication in OJ (B) [] To Chairmen and Members (C) [X] To Chairmen (D) [] No distribution

Datasheet for the decision of 11 December 2008

Case Number:	T 1389/06 - 3.3.01
Application Number:	97953377.5
Publication Number:	0963158
IPC:	A01N 31/02

Language of the proceedings: EN

Title of invention:

Hydroalcoholic compositions thickened using polymers

Patentee:

MINNESOTA MINING AND MANUFACTURING COMPANY

Opponent:

BODE Chemie Hamburg

Headword:

Hydroalcoholic compositions/MINNESOTA

Relevant legal provisions:

EPC Art. 123(3), 54, 83, 56 EPC R. 80

Relevant legal provisions (EPC 1973):

-

Keyword:

"Amendments according to Rule 80 EPC (no) - correction of printing error" "Extension of scope of protection (no) "Sufficiency of disclosure (yes)" "Novelty (yes)" "Inventive step (yes) - no incentive for the skilled person"

Decisions cited:

т 0172/99

Catchword:

-



Europäisches Patentamt European Patent Office Office européen des brevets

Beschwerdekammern

Boards of Appeal

Chambres de recours

Case Number: T 1389/06 - 3.3.01

DECISION of the Technical Board of Appeal 3.3.01 of 11 December 2008

Appellant: (Opponent)	BODE Chemie Hamburg Melanchthonstrasse 27 D-22525 Hamburg (DE)
Representative:	Kossak, Sabine Harmsen Utescher Rechtsanwälte Patentanwälte Alter Wall 55 D-20457 Hamburg (DE)
Respondent: (Patent Proprietor)	MINNESOTA MINING AND MANUFACTURING COMPANY 3M Center P.O. Box 33427 St. Paul Minnesota 55133 3427 (US)
Representative:	Vossius & Partner Siebertstrasse 4 D-81675 München (DE)
Decision under appeal:	Decision of the Opposition Division of the European Patent Office posted 7 July 2006 rejecting the opposition filed against European patent No. 0963158 pursuant to Article 102(2) EPC.

Composition of the Board:

Chairman:	P. Ranguis
Members:	G. Seufert
	CP. Brandt

Summary of Facts and Submissions

I. The Appellant (Opponent) lodged an appeal against the decision of the Opposition Division on the rejection of the opposition against the European patent No. 963 158, which was granted on the basis of 28 claims.

The four independent claims of the patent as granted read as follows:

1. An antimicrobial hydroalcoholic composition comprising:

(a) a hydroalcoholic solvent system comprising a C₁₋₄-alcohol and water in a weight ratio of at least 50:50;
(b) a thickener system comprising at least one cationic polymeric thickener that is solid at ambient temperature; wherein the cationic thickener is selected such that the composition has a viscosity of at least 10.000 centipoise at 23°C; wherein the thickener system is present in an amount of at least 0.5% by weight, based on the total weight of the composition; and
(c) a secondary antimicrobial agent.

15. An antimicrobial hydroalcoholic lotion comprising: (a) a hydroalcoholic solvent system comprising a C_{1-4} alcohol and water in a weight ratio of at least 60:40; (b) a thickener system consisting essentially of one or more nonionic polymeric thickeners, at least one of which is solid at ambient temperature and at least one of which is at least partially crosslinked, wherein the one or more polymeric thickeners are selected such that the composition has a viscosity of at least 4,000 centipoise at 23°C; and further wherein the thickener system is present in an amount of at least 0.5% by weight, based on the total weight of the composition; and

(c) a secondary antimicrobial agent.

22. An antimicrobial hydroalcoholic composition in the form of a lotion comprising: (a) a hydroalcoholic solvent system comprising a C_{1-4} alcohol and water in a weight ratio of at least 60:40; (b) a thickener system comprising at least one associative polymeric thickener that is solid at ambient temperature; wherein the associative polymeric thickener is selected such that the composition has a

viscosity of at least 4,000 centipoise at 23°C; wherein the thickener system is present in an amount of at least 0.5% by weight, based on the total weight of the composition, and

(c) a secondary antimicrobial agent.

28. A method of dispensing the composition of any one of claims 1-27 comprising dispensing said composition in a discrete and substantially uniform amount.

- II. In this decision the following numbering will be used to refer to the documents:
 - (1) EP-A-0 223 681
 - (2) US-A-5,167,950
 - J. J. de Bruin, Hydrophobically modified
 Cellulose Ether for Personal Care, SÖFW-Journal,
 vol. 120. 15/1994, pp. 944-947
 - (8) EP-A-0 689 767

- (10) Comparative examples to compositions of example 1 of the disputed patent provided by the Appellant with letter of 10 April 2006
- (13a) Comparative examples: Viscosity measurements
 (B spindle) of a composition of example 1 of the
 patent in suit comprising 2 wt.-% Celquat 230M
 and 0.5 wt.-% CHG submitted by the Appellant on 1
 June 2006
- (13b) Comparative examples: Viscosity measurements
 (C spindle) of a composition of example 1 of the
 patent in suit comprising 2 wt.-% Celquat 230M
 and 0.5 wt.-% CHG submitted by the Appellant on
 1 June 2006
- (16) Herbert P. Fiedler, Lexikon der Hilfsstoffe für Pharmazie, Kosmetik und angrenzende Gebiete, 4th edition, (1996), Editio Cantor Verlag Aulendorf, pages 946, 330, 1248
- (17) Expert opinion submitted by the Appellant with letter of 10 November 2008
- (18) Expert opinion by Dipl. Ing. L. Gehm submitted by the Appellant with letter dated 9 December 2008
- III. Opposition had been filed by the Appellant on 7 April 2004 requesting revocation of the patent in its entirety on the grounds of lack of novelty and inventive step (Article 100(a) EPC in combination with Article 54 and 56 EPC) and insufficiency of disclosure (Article 100(b) EPC in combination with Article 83 EPC).
- IV. With letter dated 30 November 2004 the Respondent (Patent Proprietor) filed a request for correction of printing errors in the patent specification, which has been accepted by the Examining Division with letter of 14 December 2004. Claim 1 was amended to read 10,000 instead of 10.000

- V. The Appellant raised objections against the corrected version under Article 123(2) and (3) EPC, as well as objections under Rule 80 EPC and Article 84 EPC.
- VI. The opposition division held that
 - (a) the subject-matter of the main request did not violate the requirement of Article 123(2) and (3) EPC and did not contravene Rule 80 EPC, as the claims were never amended in this respect by the patent proprietor during the proceedings. The corrections clearly relate to printing errors due to the poor quality of the scanned version; The values "10,000" and "60,000" refer to the values 10000 and 60000, because in the English language the comma is used as an optional separator in larger numbers and the "." is used separating whole numbers from fractions. This is different from the usage in the German language, which is the other way around.
 - (b) the opponent's objection under Article 84 EPC cannot be considered, because there has been no change in the scope of the claims and Article 84 EPC is not a ground for opposition;
 - (c) the patent in suit discloses the invention in a manner sufficiently clear and complete for it to be carried out by a skilled person.
 - (d) the subject-matter of the main request is novel over the formulation 4 of document (1).
 - (e) the subject-matter of the main request is based on an inventive step, in view of the closest prior art, document (8). Although the polymeric thickeners used in the disputed patent are known as thickeners for topical compositions, their

suitability as thickener for hydroalcoholic systems has not been described. The combination with document (2) does not lead to the present invention, because document (2) only refers to non-crosslinked nonionic cellulosic thickeners.

- VII. With his reply to the statement of the grounds of appeal the Respondent resubmitted his auxiliary request of 10 April 2006. Claim 1 of the auxiliary request differs from claim 1 of the patent as granted in that the feature of dependent claim 11 has been introduced. Independent claims 15 and 22 with their dependent claims have been deleted.
- VIII. The submissions of the Appellant during appeal proceedings can be summarised as follows:

In his statement of grounds of appeal the Appellant argued that the "amendments" requested by the Respondent with letter of 30 November 2004 were not corrections of printing errors but amendments in the sense of Rule 80 EPC (former Rule 57a EPC) to overcome the ground of opposition under Article 100(c) EPC, which has, however, not been raised. The claims have therefore been amended in the sense of Rule 80 EPC. As such they must meet all the requirements of the EPC, including the requirement of Article 84 EPC. In this context the Appellant argued that without the specification of the spindle speed the viscosity is not a clear and reliable parameter. In addition he considered the amount of salt to be an essential parameter, which is missing in the claims. The Appellant further argued that the "amended" claims of 30 November 2004 violate the requirement of Article 123(3) EPC, because they extend the scope of protection over the patent as granted. In the version as granted a viscosity of 10 mPas, equivalent to 10.000 (ten) centipoise (cps), is claimed. This value has been changed after grant to 10,000 (ten thousand) cps with the Respondent's claims filed on 30 November 2004. The Appellant contested that this change was a correction of printing errors.

The absence of the spindle speed and the amount of salt are also the Appellant's main arguments as to why the viscosity is not so clearly and completely disclosed that the skilled person can carry out the invention. The viscosity is dependent on the type of apparatus, which is used, and the spindle speed. The claims per se do not contain these parameters and in the description there are also no clear instructions which measuring conditions should be used, particularly with regard to the apparatus and spindle speed. The Appellant furthermore pointed to examples in the patent showing that the viscosity limit cannot be exactly determined, or the viscosity cannot even be measured and therefore cannot be reproduced. Moreover, example 1 of the patent shows that the invention cannot be carried out over the whole scope of the claims. To support his arguments the Appellant provided comparative examples with documents (13a/13b) and (10) and an expert opinion, documents (17) and (18), showing that the viscosity measurements are dependent on the measuring conditions and therefore do not lead to reliable values. Furthermore, the amount of salt and the degree of crosslinking of the polymers influences the viscosity. Consequently, these

parameters should have been introduced into the claims to allow the invention to be carried out by the skilled person.

Novelty of claims 1 and 15 of the main request was contested by the Appellant in view of formulation 4 of document (1), which describes, so he argued, hydroalcoholic compositions comprising an anionic thickener and, in addition, a cationic thickener.

With regard to inventive step the Appellant considered document (8), which employs a different thickener, as the closest prior art. The use of cationic, partially crosslinked nonionic, or associative polymeric thickeners, is obvious for the skilled person with regard to documents (16) or (7), which disclose the use of this type of thickener in skin care products, or with regard to the general knowledge of the skilled person, which was also reflected in document (2). According to the Appellant the viscosity is not a feature contributing to the solution, as it would be inherently present by using the thickeners of document (16) or (7). In addition the validity of this parameter for the solution of the problem is not apparent.

IX. The submissions of the Respondent during the appeal proceedings can be summarised as follows.

> The Respondent argued that the amendments filed on 30 November 2004 were corrections of printing errors, which according to the legal advice no. 17/90 (OJ EPO, 1990, 260) can be corrected any time. The values "10000" and "60000" for the viscosity have never been changed during prosecution and were the result of

printing errors associated with the scanning process used by the EPO. The correction of misprints, however, cannot contravene Article 123(2), (3) EPC, or Article 84 EPC.

In response to the grounds under Article 100(b) EPC the Respondent argued that the patent in suit contains sufficient information in the paragraphs [0030], [0080] and [0081] on how the viscosity is to be measured. In addition, the spindle speed is defined in the patent in suit in view of the definition that the viscosity is taken at the lowest speed possible while staying within 20-80% of the viscometer range. The viscosity experiments provided by the Appellant with document (13a/13b) are not relevant as they were apparently taken on a different viscometer using different spindles and no heliopath adapter. The amount of salt or the degree of crosslinking do not need to be specified, since the viscosity is measured on the final composition, thus taking care of any influence these parameters might have on the viscosity of the composition. With regard to the examples of the patent, which have been pointed out by the Appellant, the Respondent considered these examples as comparative examples. With regard to enablement over the whole breadth the Respondent argued that the claims relate to hydroalcoholic compositions defined by the components and the viscosity. The fact that some of the examples of the patent or those of document (10) do not possess a viscosity in the required range simple means that they are not compositions according to the invention. The Respondent contested the relevance of the expert opinion of 10 November 2008 and 9 December 2008, documents (17)/(18). In his opinion the reading of the

- 8 -

data does not appear to be from a LVDV viscometer and it is not apparent that the expert followed the instruction of the patent with regard to the definition of the spindle speed.

The Respondent rejected the argument of the Appellant that document (1) anticipates the subject-matter of the patent in suit. Formulation 4 of document (1) merely refers to a relatively broad range of theoretical compositions with no viscosity data. Document (1) contains a general statement as to the viscosity, i.e. at least 40 cps, but recommends a viscosity range of 50 to 500 cps, well below the range disclosed in the patent in suit. The Appellant who has the burden of proof has not shown that formulation 4 of document (1) in fact shows the required viscosity. In addition, hydroxypropyl cellulose is not a crosslinked anionic thickener.

The Respondent also considered document (8) as the closest prior art. He argued that none of the documents (16) or (7) provided a motivation for the skilled reader to replace the thickeners of document (8), because none of these documents teaches the suitability of the polymers defined in the claims thickening agents in hydroalcoholic composition with high amounts of alcohol. In addition, the claimed thickeners provide additional advantages, for example the cationic polymers do not "ball up" unlike the nonionic thickeners of document (8).

X. The Appellant requested that the decision under appeal be set aside and that the patent be revoked. The Respondent requested that the appeal be dismissed or, in the alternative, that the patent be maintained on the basis of the auxiliary request filed on 10 April 2006.

XI. At the end of the oral proceedings held on 11 December 2008 the decision of the Board was announced.

Reasons for the Decision

1. The appeal is admissible.

Main request

- 2. Amendments
- 2.1 The application as filed disclosed and claimed compositions with a viscosity of "10,000" (ten thousand) and "60,000" (sixty thousand). In the patent as granted these values had been changed to 10.000 (ten) and 60.000 (sixty). Only after opposition had been filed has the Respondent requested with letter of 30 November 2004 the correction of these values and has corrected the viscosity again to 10,000 and 60,000 (ten thousand and sixty thousand). The Appellant argued that the amendments filed by the Respondent on the 30 November 2004 are amendments in the sense of Rule 80 EPC in order to overcome the

ground of opposition under Article 100(c) EPC. They were not corrections of printing errors.

2.2 According to Rule 80 EPC the description, claims and drawings may be amended provided that the amendments

are occasioned by a ground for opposition under Article 100 EPC, even if that ground has not been invoked by the opponent.

- 2.3 The Board observes that according to the legal advice 17/90 printing errors may be corrected at any time by the Office. The request for correction has been dealt with and accepted by the **Examining Division** with letter of 14 December 2004. The Board is therefore of the opinion that the Respondent has not amended his claims before the Opposition Division in the sense of Rule 80 EPC.
- 2.4 With regard to the argument of the Appellant that the requested corrections of the viscosity values were not corrections of printing errors, the Board can see no legal basis allowing it to re-examine the decision of the Examining Division accepting the corrections.
- 2.5 The ground of opposition under Article 100(c) EPC under which it could have been examined whether the patent as granted as a consequence of the correction extends beyond the application as originally filed, has not been raised with the statement of grounds of appeal and has not been considered by the Opposition Division either. Therefore, this argument also cannot succeed.
- 3. Extension of the scope of protection in the sense of Article 123(3) EPC
- 3.1 The Appellant argued that the claims submitted with letter of 30 November 2004 extend beyond the scope of protection conferred by the patent. The patent as granted refers to an antimicrobial hydroalcoholic

composition with a viscosity of 10 mPas (10 cps). This value has been amended to 10000 mPas (10000 cps). Again the Appellant contested that these amendments are a correction of printing errors.

- 3.2 The Board notes that the Examining Division has accepted the request for correction by the Respondent. Thus, the corrected version of 14 December 2004 corresponds to the patent as granted. It follows from this that the corrected version cannot extend the scope of protection in the sense of Article 123(3) EPC.
- 4. Clarity of the claims
- 4.1 In the Appellant's view the claims of the patent in suit have been amended during opposition proceedings. In accordance Article 101(3)a) EPC (former Article 102(2) EPC) these amendments must meet the requirements of the EPC, which includes the requirement of clarity according to Article 84 EPC. In this context the Appellant argued that the viscosity of a composition is essentially dependent on the spindle speed employed during the measurement and the amount of salt present in the composition. The absence of both parameters renders the claims unclear.
- 4.2 The Board has come to the conclusion that the claims have not been amended in the sense of Rule 80 EPC before the Opposition Division (supra, point 2.3). Since Article 84 EPC is not a ground of opposition the Board has no power to decide on this issue in view of the fact that the claims as granted have not been amended.

5. Insufficiency of disclosure of the invention

- 5.1 According to Article 83 EPC, the European patent application must disclose the invention in a manner sufficiently clear and complete for it to be carried out by the skilled person.
- 5.2 The independent claims 1, 15 and 22 of the patent in suit refer to hydroalcoholic compositions comprising cationic, partially crosslinked anionic or associative polymeric thickeners selected such that the compositions have a viscosity of at least 10000 or at least 4000 cps at 23°C and wherein the thickener is present in at least 0.5% by weight based on the total weight of the composition.
- 5.3 The Appellant based his objection of insufficiency of disclosure on the arguments that the exact method of measuring the viscosity and particularly the spindle speed were not indicated. In addition, the amount of salt and degree of crosslinking were not present, examples in the patent in suit provided evidence that the viscosity of the composition could not be determined, and the invention could not be carried out within the whole scope of the claims.
- 5.3.1 Although the claims require that the composition has a certain viscosity, they do not contain a method by which this parameter is measured. According to the Appellant the determination of the viscosity is essentially dependent on the spindle speed and the apparatus to be used. The important influence of the spindle speed on the viscosity measurement was already apparent from the patent in suit (page 14, paragraph

[0089]), where the viscosity increased by 33% when the spindle speed was halved. It was further illustrated by the Appellant's own examples, documents (13a)/13(b) and (17)/(18), which demonstrate that the viscosity of a composition can vary considerably by using different viscometers and measuring conditions, particularly different spindle speeds. Although the description of the patent in suit mentions the use of a specific viscometer in paragraph [0080], the same paragraph contains the statement **except where indicated**, without indicating any other method for measuring the viscosity. In addition, other viscometers are also used in the examples of the patent in suit. The spindle speed can also not unambiguously be determined by reference to an apparatus, for example its instruction, because the technical data of an apparatus may change due to further technical development of the apparatus. Thus, depending on the choice of apparatus and spindle speed any viscosity can be measured for a given composition and the skilled person can create compositions which either fall within the ambit of the claims or not. In the absence of reliable values in the claims, which are independent of the measuring conditions, it is not possible for the skilled person to establish the limit of the claims. Consequently, he or a third party would not be able to determine whether they worked within the scope of the claims or outside. Furthermore, the Appellant relying on documents (17)/(18) argued that the method of measuring the viscosity indicated in the patent in suit is not the best and most suitable method.

5.3.2 The Board notes that the absence of a method for the determination of the viscosity values from the

independent claims does not necessarily mean that the invention is insufficiently disclosed. The relevant question is rather whether the patent in suit provides sufficient information which enables the skilled person taking into account common general knowledge to reproduce the claimed compositions.

- 5.3.3 According to the patent in suit the viscosity is measured using a **very low shear viscometer** (page 4, lines 28-31), such as the Brookfield LVDV-1+ viscometer and T spindles with a heliopath adapter. Furthermore, paragraphs [0080] and [0081] of the patent in suit describe in more detail the conditions under which the viscosity is measured using the aforementioned low shear Brookfield viscometer. The viscosity is taken at the lowest speed possible while staying within 20-80% of the viscometer range. The viscosity of each sample was taken as the highest relatively stable reading achieved on the first path the spindle traversed using the heliopath adapter. All these conditions serve the purpose of avoiding shear effects which could distort the viscosity values. This is in line with the patent in suit page 14, lines 39 - 40 illustrating the influence of higher rotational speeds on the viscosity. In order to take into account the influence of other ingredients the viscosity is measured on the final composition.
- 5.3.4 It is the Board's opinion that the patent in suit provides the skilled reader with a clear indication that the viscosity should be measured in such a way as to avoid shear effects. It mentions a suitable viscometer in form of the specified Brookfield viscometer. The skilled person knowing that shear

- 15 -

effects should be avoided will use the viscometer described in the patent in suit or may select a different equally suitable low shear viscometer.

- 5.3.5 With regard to the spindle speed, the Board agrees with the Appellant that a specific value for the spindle speed is not mentioned in the disputed patent. However, the Board shares the opinion of the Respondent that the spindle speed is indirectly defined by the definition that the viscosity measurement is taken at the **lowest spindle speed possible while staying within 20-80% of the viscometer range**. Thus, for each specific example there is only one speed, which is **the lowest** while staying within the required viscometer range.
- 5.3.6 With regard to the experimental reports, documents (13a)/(13b), the Board notes that the viscosity is not measured according to the method indicated in the patent in suit. A different viscometer is used and there are no indications that the measurements had been carried out according to the instruction given in paragraphs [0080] and [0081] of the patent in suit. Nevertheless, in the documents (13a)/(13b), using a composition according to example 1 of the disputed patent, the viscosity, although not measured according to the method indicated in the patent in suit, falls within the claimed range. Only, with very high spindle speeds, for example 20 rpm or 50 rpm, at which shear effects might occur, which is against the teaching of the patent, is a viscosity lower than required obtained.
- 5.3.7 The experimental reports (13a)/(13b) therefore cannot be used as evidence for insufficiency of disclosure and cannot support the Appellant's case. They show that

compositions of the patent in suit have the required viscosity even when measured on different viscometers. Only when going against the disclosure of the patent can viscosities outside the required scope be obtained for the same compositions. Varying results, in the Board's opinion, do not necessarily disable a person skilled in the art to put the invention into practice, but are rather related to the question whether the invention is correctly defined in accordance with Article 84 EPC.

- 5.3.8 A similar conclusion can be drawn with regard to the expert opinion, documents (17)/(18), provided. According to the Appellant the viscosity measurements on a composition according to example 1 of the patent in suit have been carried out on a LVDV-I+ viscometer. It is however not apparent that the viscosity has been measured according to the instructions of the patent in suit. Documents (17)/(18) merely state that the viscosity has been measured at speed of 6, 12, 30 and 60 s⁻¹. Whether the value 6 s⁻¹ is the **lowest possible** speed while staying within the 20-80% of the viscometer range is not apparent. Notwithstanding the difference in spindle speed, the Board notes that all the measurements are within the claimed range.
- 5.3.9 With regard to the Appellant's argument that the viscosity measurement indicated in the patent in suit is not the best and most suitable way of measuring this parameter, the Board is of the opinion that for the sufficiency of disclosure it is not necessary to use the best and most suitable way, as long as sufficient information is present on how the viscosity according to the patent in suit should be measured.

- 5.3.10 The Appellant's arguments that the absence of any measuring condition or the absence of a parameter, which is independent of the measuring conditions, does not allow the skilled reader to define whether he works within or outside the scope of the claims, are considered by the Board to be more concerned with the question whether the viscosity is a clear and reliable parameter. This objection by the Appellant concerns more the determination of the limits of protection and not the possibility for the skilled person to reproduce the claimed composition.
- 5.3.11 Apart from the question of how the viscosity has to be measured, the Appellant argued that the amount of salt as well as the degree of crosslinking in addition to the spindle speed significantly influence the viscosity. The absence of these parameters from the claims does not allow the skilled person to reproduce the claimed compositions.
- 5.3.12 The Board does not share the Appellant's point of view. Although it is correct that the viscosity can be influenced by these parameters, as the patent in suit already shows, the viscosity is measured on the **final** product (page 4, lines 29 - 31), which therefore takes into account any effect, which may be exerted by the salt content or the amount of crosslinking, or by any other ingredients. The absence of specific data concerning the amount of salt or the degree of crosslinking in the independent claims does not render the claimed subject-matter insufficiently disclosed or irreproducible.

5.3.13 To further support his objection of insufficiency of disclosure, the Appellant pointed to various examples in the patent in suit (example d on page 19 and examples T, U and V on page 23), which in his opinion demonstrated that the viscosity cannot be measured so accurately that the skilled person can reproduce the invention. Furthermore, the Appellant, relying on example 1 of the disputed patent, argued that the invention cannot actually be carried out over the whole scope of the claims. In example 1 the use of the polymers Celquat 230M and Celquat H-100, which are cationic polymers according to the invention, does not necessarily lead to compositions with the required viscosity. To support this argument, the Appellant provided further examples, document (10), wherein he prepared compositions according to example 1 of the patent in suit using Celquat 230M as thickener in a concentration of 1, 2 or 0.5 wt% . These comparative examples show that Celquat in a concentration of 1 or 0.5 wt% does not lead to compositions with the required viscosity.

5.3.14 The Board cannot follow the Appellant's arguments. Example d is not an example according to the invention, because it does not contain a second antimicrobial agent. Furthermore, isolated examples exhibiting a certain viscosity range do not constitute evidence that the viscosity cannot be exactly determined. As pointed out by the Respondent, other factors, like incomplete mixing may be responsible for such an effect. Equally, examples T, U and V cannot be considered as evidence that the invention is insufficiently disclosed or that the viscosity cannot be determined. These examples merely state that the viscosity of the compositions is

lower than the detection limit of the viscometer. With regard to example 1 of the patent in suit it is the Board's opinion that this example merely illustrates that different polymers may have to be employed in different amounts depending on the degree of their thickening capability. It provides further information to the skilled person on how to prepare compositions according to the invention: for example the use of Celquat 230M in a concentration at 1 wt% does not lead to compositions with the required viscosity, but a concentration of 2 wt% does. The comparative examples provided by the Appellant do not show anything more than is already described in the patent itself. They show that using even less than 1 wt.% does not lead to compositions with the required viscosity, which in view of example 1 of the disputed patent is not surprising. The Appellant's argument that claim 1 requires that the viscosity should be achieved at an amount of 0.5% by weight cannot be followed. Claim 1 requires that the thickener is selected such that the required viscosity is achieved **and** that it is present in at least 0.5% by weight. This wording does not imply that the viscosity has to be achieved at 0.5% by weight of the thickener.

5.4 For the reasons set out above the Board concludes that the patent in suit provides the skilled person with sufficient guidance on how to put the invention into practice and on how to provide further compositions which fall within the ambit of the claims. The requirement of Article 83 EPC is therefore fulfilled.

6. Novelty

- 6.1 The Appellant disputed the novelty of the subjectmatter of the patent in suit in view of the disclosure of document (1), in particular in view of formulation 4 on page 6 of document (1).
- 6.2 The Board notes that it is a generally applied principle that for concluding lack of novelty, there must be a direct and unambiguous disclosure in the state of the art which would directly and inevitably lead the skilled person to the subject-matter falling within the scope of what is claimed. Furthermore, before the Opposition Division as well as before the Board, it is the Opponent who bears the burden of proof as regards demonstrating that the patent does not fulfil the requirement of the EPC.
- 6.3 Document (1) refers to alcohol-based skin disinfectant compositions comprising (a) 30 to 90 percent alcohol, based on total composition weight, (b) 0.1 to 10 percent alcohol-soluble viscosifying agent, based on total composition weight, and c) the balance water (see document (1), claim 6). The viscosifying agents produce compositions of at least 40 cps, more preferably 50 to 500 cps (page 3, lines 15-22). On page 6 of document (1) formulation 4 is mentioned having 30-75 g isopropyl alcohol, 0.25-5.0 g hydroxypropyl cellulose, 10-60 ml water, 0.1-0.2% parachloro-meta-xylenol (an antimicrobial agent), and further components. As one of the additional components

a polymer of **dimethyldiallyl ammonium chloride** (Merquat 100) is mentioned as emollient. No viscosity data is mentioned in combination with formulation 4.

- 6.4 The Appellant argued that formulation 4 of document (1) discloses compositions falling within the scope of claim 15. Formulation 4 contains hydroxypropyl cellulose, which is an anionic thickener commercially available under the name "Klucel" (document 1, page 3, line 33 - page 4, line 8). Hydroxypropyl cellulose or "Klucel" is also mentioned as a nonionic thickener in the disputed patent (page 6, lines 45-46). The Appellant concludes that by using one of the exemplified nonionic thickeners of the patent in suit the viscosity required in claim 15 is automatically achieved. In addition, the Appellant referred to page 3, line 18 of document (1), where a composition viscosity of at least 40 cps is mentioned, which merely represents the lower limit of the viscosity, but does not exclude significantly higher viscosity values.
- 6.5 The Board notes that claim 15 of the disputed patent refers in feature (b) to "a thickener system consisting essentially of one or more **nonionic** polymeric thickeners at least one of which is at least **partially crosslinked**". Formulation 4 of document (1) describes compositions with hydroxypropyl cellulose as thickener. However, document (1), and in particular formulation 4, does not disclose the feature that the hydroxypropyl cellulose is at least partially crosslinked. The Respondent has already during opposition procedures pointed out that hydroxypropyl cellulose is usually not crosslinked, and the Appellant, who bears the burden of proof for demonstrating lack of

novelty, has not provided any evidence that hydroxypropyl cellulose, for example the commercially available product "Klucel" as mentioned in document (1), is by definition at least partially crosslinked. Thus, document (1), for this reason alone, cannot anticipate the subject-matter of claim 15 of the patent in suit.

- 6.6 The Appellant also contested novelty of the subjectmatter of claim 1 of the disputed patent. According to the Appellant document (1) discloses hydroalcoholic compositions with a viscosity of at least 40 cps (erroneously the Appellant mentioned the value 400 cps) comprising a cationic thickener in the form of a polymer of dimethyldiallyl ammonium chloride.
- 6.7 Claim 1 of the patent in suit refers in feature (b) to "a thickener system comprising at least one cationic polymeric thickener ... wherein the cationic thickener is selected such the composition has a viscosity of 10000 cps". Merquat 100 falls within the definition of a cationic polymer. However, document (1) is completely silent with regard to any thickening properties of this polymer. In formulation 4 of document (1) Merquat 100 is added as emollient. Document (1), and in particular formulation 4, does not provide a direct and unambiguous disclosure to use Merquat 100 as a cationic thickener suitable to provide hydroalcoholic compositions comprising the claimed solvent system and having a viscosity of 10000 cps. The Appellant has also not provided any evidence demonstrating that the use of Merquat 100 in the amount disclosed in formulation 4 of document (1) can act as a

thickener in hydroalcoholic compositions with the required high amount of alcohol in the solvent system.

- 6.8 For the reasons set out above the Board concludes that the subject-matter of claim 1 and 15 of the patent in suit is novel within the meaning of Articles 52(1) and 54(1) and (2) EPC.
- 7. Inventive step
- 7.1 According to established jurisprudence of the Boards of Appeal, it is necessary, in order to assess inventive step, to establish the closest state of the art, to determine in the light thereof the technical problem which the invention addresses and successfully solves and to examine the obviousness of the claimed solution to this problem in view of the state of the art. This "problem-solution approach" ensures assessing inventive step on an objective basis and avoids an ex post facto analysis.
- 7.2 The patent in suit is directed to antimicrobial hydroalcoholic compositions comprising a high amount of a C₁₋₄-alcohol, i.e. alcohol and water in a weight ratio of at least 50:50 or 60:40, a thickener system comprising cationic, partially crosslinked nonionic or associative thickeners selected such that a viscosity of at least 10000 cps (cationic thickeners) or at least 4000 cps (crosslinked nonionic or associative thickeners) is achieved, and a secondary antimicrobial agent. The compositions are useful as surgical hand preparations and antimicrobial hand lotions for healthcare professionals in order to control infections.

7.3 Similar compositions already belong to the state of the art. Document (8) describes antimicrobial hydroalcoholic compositions with a high amount of alcohol, i.e. 50 to 80% by weight of alcohol and 6 to 30% by weight of water, for the same purpose, namely skin disinfection for healthcare professionals. The compositions according to document (8) further comprise 0 to 5% of a preservative, which has antimicrobial effects (document (8), page 5, lines 11-17), 0 to 3% of a thickening agent and further components (document (8), page 2, lines 31-55, claim 1). Suitable thickeners according to document (8) are nonionic polymeric thickeners, like starch, methyl cellulose ethers or hydroxyethyl cellulose, or nonionic surfactants (document (8), page 4, lines 42-56). In table 1 on page 7 of D8 reference is made to the composition 341-E1, with 70% by weight of isopropyl alcohol, 6.5% by weight of water, 1% by weight of Methocel 40-100 as thickener, and 2.5% by weight of the antimicrobial agent chlorhexidine gluconate (20%), and further components.

- 7.4 Thus, the Board considers, in agreement with the Appellant and the Respondent, that document (8) represents the closest state of the art and, hence takes it as the starting point for assessment of an inventive step.
- 7.5 According to page 2, lines 46 56 it was an object of the patent in suit to provide hydroalcoholic compositions with a good balance of properties that are desirable for skin disinfectants. In particular, the claimed compositions should be viscous and cosmetically elegant, substantially non tacky, easy to wash off with water, compatible with cationic components and should

also maintain or even improve skin condition, thereby overcoming the shortcomings of past compositions.

- 7.6 It is established jurisprudence of the Boards of Appeal that advantageous properties or effects, if they have been appropriately demonstrated by means of truly comparable results, could in certain circumstances form a basis for the definition of the technical problem the invention sets out to solve. The only comparative tests suitable for this are, however, those which compare the structurally closest state of the art with the invention.
- 7.7 In the present case there is no direct comparison between the claimed antimicrobial compositions and the antimicrobial compositions disclosed in document (8). Furthermore, the compositions of document (8) are described as non irritant to the skin. They do not dry the skin, have good foaming properties, good solubility in water and adequate detergency. Due to the use of nonionic thickeners, no compatibility problem with a cationic antimicrobial agent should occur.
- 7.8 It is thus not apparent that the compositions according to the patent in suit have any advantageous properties or beneficial effects compared to those of the prior art disclosed in document (8). Since no such properties or effects can be acknowledged, the Board, in agreement with the Appellant, considers the problem to be solved by the present invention to be the provision of alternative antimicrobial hydroalcoholic compositions comprising a hydroalcoholic solvent system with a high amount of alcohol.

7.9 As the solution to the underlying technical problem the patent in suit proposes the use of cationic thickeners, at least partially crosslinked nonionic thickeners, or associative thickeners, selected such that a high viscosity is achieved.

- 7.10 Taking into account the information in the examples of the patent in suit the Board is satisfied that the problem has been solved.
- 7.11 The question which remains to be decided is therefore whether or not the proposed solution to the problem underlying the patent in dispute is obvious in view of the cited prior art.
- 7.11.1 The Appellant argued that it is first of all trivial to use a cationic thickener to avoid compatibility problems with cationic agents in the composition. Furthermore, substituting the nonionic thickener of document (8) by a cationic thickener is obvious for the skilled person in view of his general knowledge, reflected in document (16). This document, which is an excerpt from a lexicon for excipients in pharmacy, cosmetics and related areas, describes the product Polyquaternium-10 or Celquat SC-230M as cationic polymer useful as skin compatible thickener in cosmetic preparations. Polyquaternium-10 or Celquat SC-230M is also a preferred cationic thickener according to the invention as exemplified in example 1 of the patent in suit. The Appellant concluded that the viscosity of 10000 cps is inevitably achieved by using the cationic thickener Celquat SC-230M in the composition 341-E1 of document (8).

7.11.2 The Board is of the opinion that replacing the anionic thickeners with a cationic thickener cannot be considered trivial as long as the skilled person is not aware of the fact that the cationic thickeners are suitable for the specific solvent system employed by

aware of the fact that the cationic thickeners are suitable for the specific solvent system employed by the patent in suit. The Appellant's argument that this suitability is common general knowledge, as can be seen from document (16), is not convincing. Document (16) is completely silent with regard to thickening properties of Celquat SC-230M in hydroalcoholic compositions comprising a hydroalcoholic solvent system with the required high amount of alcohol. It discloses the usefulness of Celquat SC-230M in cosmetic preparations, like hair and skin care products. However, these products usually do not comprise such a high amount of alcohol as required for hand disinfection preparation. In addition, the Board observes that document (8) also requires that the thickener should be soluble in about 70% alcohol (page 4, line 41). Document (16) describes that Celquat CS-230M is soluble in water, but insoluble in **ethanol**. No information is given as to the solubility in solvent systems of about 70% alcohol.

The skilled person had therefore no reason or motivation to consider replacing the known and apparently suitable nonionic thickener of document (8) by cationic thickeners represented for example by Celquat SC-230M in order to solve the technical problem. Whether or not the viscosity required by claim 1 would be automatically obtained if the thickener in the composition 341-E1 of document (8) is replaced by Celquat CS-230M is of no relevance in the absence of any incentive for the skilled person to do so. 7.11.3 The Appellant furthermore contested the validity of this parameter for the solution of the technical problem and referred in this context to the decision T 172/99, catchword and point 4.5.6.

- 7.11.4 With regard to the decision T 172/99 it is the opinion of the Board that the case underlying this decision cannot be compared to the present case. In T 172/99 the Patent Proprietor relied on a "newly formulated and, hence, unfamiliar parameter to define the solution to a technical problem by which a relevant effect is achieved", cf. catchword and paragraph 4.5.6 of T 172/99. Furthermore, in T 172/99 certain effects to be achieved, namely gloss and high impact strength, were related to the unusual and unfamiliar parameter. In the present case the viscosity can hardly be considered as an unusual or unfamiliar parameter for the skilled person and no specific effects are related to the viscosity parameter.
- 7.11.5 The Appellant relied on basically the same line of arguments with regard to the use of a thickener system consisting essentially of one or more nonionic polymeric thickeners at least one of which is at least partially crosslinked selected such that a viscosity of at least 4000 cps is achieved (claim 15), or a thickener system comprising at least one associative polymeric thickener selected such that a viscosity of at least 4000 cps is achieved (claim 22). According to the Appellant the replacement of the nonionic thickener of composition 341-E1 in document (8) by one of the aforementioned thickeners is obvious for the skilled person in view of document (7). This document describes, so he argued, the **associative thickener** "Natrosol Plus".

Figure 1 of document (7) refers to its use in hydroalcoholic skin care products and in the left column on page 945 it is stated that Natrosol Plus grade 330 CS offers the possibility in certain formulations to give viscosity equal to high molecular weight material. Its compatibility with ionic ingredients is disclosed on page 946, left column, last paragraph. In the opinion of the Appellant Natrosol Plus can also be considered as a **crosslinked nonionic thickener**, as can be seen on page 946, middle column last line to right column.

7.11.6 The Appellant's arguments with regard to the teaching of document (7) are not considered convincing. The Board notes that figure 1 of document (7) does not refer to the application of Natrosol Plus, but to the application of the cellulose ethers known in the prior art, for example the known hydroxypropyl cellulose. Document (7) is completely silent as to the suitability of Natrosol to act as a thickener in hydroalcoholic compositions with the high amount of alcohol as presently claimed. It describes the application of Natrosol Plus grade 330 CS in a shampoo and hand & body lotion formulation. Both are aqueous compositions without or with very low amounts of alcohol (i.e. glycerol in the hand & body lotion). With regard to the term "crosslinked", the Board is of the opinion that, although document (7) uses this term, it is obvious from this document that the Natrosol is not so much a crosslinked polymer as a "protected" or "capped" polymer, which has to hydrolyse in water before building up viscosity (document (7), page 946, middle column, last line - right column, line 9.

7.11.7 The Board thus comes to the conclusion that document (7) does not present an incentive for the skilled person to replace the thickener in document (8) with the thickener of document (7).

- 7.11.8 Furthermore, the Appellant interpreted the statement in document (8) which refers to the advantages and disadvantages of more hydrophobic and less hydrophilic thickener, as an incentive for the skilled person to use associative thickeners as claimed.
- 7.11.9 The Board does not share the Appellant's interpretation of the statement in document (8). Although it can be accepted that associative thickeners can be considered as hydrophobic thickeners due to their long alkyl side chains, it cannot be concluded vice versa that the use of the term "hydrophobic" in document (8) automatically points to associative thickeners. Document (8) refers in the paragraph directly in front of the aforementioned statement by the Appellant to different anionic thickeners, for example starch, methylcellulose, hydroxyethylcellulose, pluronic surfactants and even acrylic acid polymers (i.e. anionic polymers). These polymeric thickeners undoubtedly differ in their hydrophobic or hydrophilic properties. The statement following this paragraph and referred to by the Appellant is seen by the Board as merely referring to the advantages and disadvantages of more hydrophobic and less hydrophilic thickeners. It does not point the skilled person to the claimed associative thickeners.
- 7.12 For the reasons set out above the Board concludes that the subject-matter of the independent claims 1, 15 and 22, and consequently claim 28 referring to these claims,

C0531.D

involves an inventive step within the meaning of Articles 52(1) and 56 EPC.

Auxiliary request

8. Having come to the conclusion that none of the grounds of opposition prejudices the maintenance of the European patent, there is no need for the Board to decide on this request.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

M. Schalow

P. Ranguis