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## Datasheet for the decision of 16 February 2012

T 0406/08 - 3.3.10 Case Number:

Application Number: 99300394.6

Publication Number: 930065

IPC: A61K 7/48, A61K 7/50,

A61L 2/00, A61L 2/18

Language of the proceedings: EN

#### Title of invention:

Alcohol based anti-microbial compositions with cosmetic appearance

## Patent Proprietor:

ETHICON, INC.

#### Opponent:

Bode Chemie GmbH

#### Headword:

Alcohol-based anti-microbial compositions/ETHICON

## Relevant legal provisions:

EPC Art. 54, 56, 83, 123(2)(3)

#### Keyword:

"Main request, auxiliary requests I and II; sufficiency of disclosure of invention (yes) - novelty (yes) - inventive step (no) - obvious alternative"

"Auxiliary requst III: Inventive step (yes) - solution not obvious from prior art"

## Decisions cited:

T 0409/91, T 0435/91, T 0182/89

#### Catchword:



#### Europäisches **Patentamt**

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Beschwerdekammern

Boards of Appeal

Chambres de recours

Case Number: T 0406/08 - 3.3.10

DECISION of the Technical Board of Appeal 3.3.10 of 16 February 2012

Appellant: Bode Chemie GmbH (Opponent) Melanchthonstrasse 27 D-22525 Hamburg (DE)

Representative: Kossak, Sabine

Harmsen Utescher

Rechtsanwälte Patentanwälte

Neuer Wall 80

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ETHICON, INC. Respondent: U.S. Route 22 (Patent Proprietor) Somerville

New Jersey 08876 (US)

Representative: Mercer, Christopher Paul

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Decision under appeal: Decision of the Opposition Division of the

European Patent Office posted 27 December 2007 rejecting the opposition filed against European patent No. 930065 pursuant to Article 101(2)

EPC.

Composition of the Board:

Chairman: P. Gryczka C. Komenda Members:

F. Blumer

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## Summary of Facts and Submissions

I. The Appellant (Opponent) lodged an appeal against the decision of the Opposition Division which rejected the opposition against the European patent No. 930 065.

The European patent was granted on the basis of 9 claims, independent claim 1 of which read as follows:

- "1. An antimicrobial composition comprising at least about 40 percent by weight alcohol, an effective amount of a carbomer polymer wherein the carbomer polymer is a modified acrylic copolymer comprising a major portion of a monoolefinically unsaturated carboxylic acid monomer or its anhydride having a length of from 3 to 6 carbon atoms and a minor portion of a  $C_8$ - $C_{30}$  chain acrylate or methacrylate ester monomer wherein the, carboxylic acid or its anhydride is from 80 to 99% by weight and the  $C_8$ - $C_{30}$  chain acrylate or methacrylate ester monomer is from 1 to 20% by weight an effective amount of a cationic antimicrobial compound, and water; the composition having a viscosity of greater than about 5,000 centipoise."
- II. Notice of Opposition had been filed by the Appellant requesting revocation of the patent as granted in its entirety on the grounds of insufficient disclosure of the invention (Article 100(b) EPC), lack of novelty and of inventive step (Article 100(a) EPC). Inter alia the following documents were submitted during opposition proceedings:

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- (7) Domsch, "Die kosmetischen Präparate", Band III,
  Lipidhaltige und emulgierte Formulierungen, Verlag
  für chem. Industrie, Augsburg (1994), S. 268,
- (8) Henkel, "Kosmetik Modellrezepturen", Sammlung von Modellrezepturen zur Herstellung von kosmetischen Präparaten unter Verwendung der Henkel Dehydag-Produkte, Ausgabe 1987,
- (9) Patent Abstracts of Japan of JP-A-0 430 5504,
- (9a) computer translation into English of JP-A-0 430 5504 and
- (10) Experimental Test Data submitted by the Respondent with Fax dated 11 October 2007.
- III. In the decision under appeal the Opposition Division held that the invention was disclosed in a manner sufficiently clear and complete for it to be carried out by a skilled person, since the patent in suit contained numerous examples of various compositions and the experimental test data according to document (10) demonstrated that compositions having the claimed viscosities can reliably be produced. Further, the subject-matter of the claims as granted was novel over documents (7), (8) and (9)/(9a), since neither of these documents discloses compositions comprising a carbomer polymer falling within the specifications as claimed in the patent in suit. Starting from document (9)/(9a) as closest state of the art the technical problem was to provide an alternative composition. However, none of the cited documents gave the skilled person any incentive to modify the compositions known from document (9)/(9a) by replacing the carboxyvinylpolymer with the claimed carbomer polymer, to further include a quaternary ammonium salt and to set the viscosity to greater than 5000 centipoise. Therefore, the claimed

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subject-matter satisfied the requirements of Articles 56 EPC.

- IV. In its statement of the grounds for appeal the Appellant repeated its objection that the invention was not disclosed in a manner sufficiently clear and complete for it to be carried out by a skilled person. Starting from document (9)/(9a) the subject-matter of the patent-in-suit does not involve an inventive step, since it was obvious to replace the thickening agents used in the closest prior art by the claimed carbomer polymers, such as Ultrez 10. In support thereof he filed document
  - (11) BF Goodrich CP26 "Brochure Carbopol polymers for thickening, suspending and stabilising", August 1995.

During oral proceedings held on 16 February 2012 before the Board the Appellant formally withdrew its auxiliary requests filed with the statement of the grounds for appeal, namely that the Board should decide whether or not the polymer "Ultrez 10" was a carbomer polymer falling within the definition of claim 1 of the patent in suit and that, if "Ultrez 10" does not fall within the definition of the carbomer polymer according to claim 1, the passages in the description, which relate to "Ultrez 10" be deleted.

V. The Respondent (Patentee) defended the maintenance of the patent in its granted form as main request. With letter dated 18 September 2008, it filed auxiliary requests I, II and III, all these requests being

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identical to the auxiliary requests I, II and III as filed on 7 November 2007 before the Opposition Division.

Claim 1 of the auxiliary request I was based on the wording of granted claim 1, wherein the "cationic antimicrobial compound" was further specified as being "benzalkonium chloride, methyl benzethonium chloride or cetyl pyridinium chloride".

Claim 1 of the auxiliary request II was based on the wording of granted claim 1, which was further restricted by appending the feature "wherein the total cationic compound level is from 0.05 to 0.5% by weight" to the end of claim 1.

Claim 1 of the auxiliary request III was based on the wording of claim 1 of the auxiliary request II, wherein the "cationic antimicrobial compound" was further specified as being "benzalkonium chloride, methyl benzethonium chloride or cetyl pyridinium chloride" and the presence of "cetyl lactate from 0.3 to 1.5 weight percent and  $C_{12}$ - $C_{15}$  alkyl lactates from 0.2 to 2.0 weight percent" was claimed.

VI. The Respondent stated that there was no evidence that the claimed invention could not be carried out by a skilled person, the doubts raised by the Appellant being not supported by the facts. None of the documents (7), (8) or (9)/(9a) disclosed the subject-matter of claim 1, which was thus novel. Starting from document (9)/(9a) as closest state of the art it was not obvious to use the carbomer polymers as claimed in the patent in suit instead of the thickening agents used in the prior art.

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VII. 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, subsidiarily, that a patent be granted on the basis of any of his auxiliary requests I to III, submitted with letter dated 18 September 2008.

VIII. At the end of oral proceedings the decision of the Board was announced.

#### Reasons for the Decision

1. The appeal is admissible.

Main request

- 2. Sufficiency of disclosure of the invention
  (Article 100(b) EPC)
- 2.1 The Appellant challenged the finding of the Opposition Division that the subject-matter of claim 1 could be carried out by a person skilled in the art so that the invention was insufficiently disclosed in the sense of Article 83 EPC.
- 2.2 It is the established jurisprudence of the Boards of Appeal that the requirements of sufficiency of disclosure are only met if the invention as defined in the claims can be performed by a person skilled in the art across the whole area claimed without undue burden, using common general knowledge and having regard to further information given in the patent in suit (see

decisions T 409/91, OJ EPO 1994, 653, point 3.5 of the reasons; T 435/91, OJ EPO 1995, 188, point 2.2.1 of the reasons). Therefore, it has to be established whether or not the patent in suit discloses sufficient information to enable the skilled person to carry out the claimed invention.

2.3 The Appellant submitted in particular, that the examples of the patent in suit did not fall within the claims, since he doubted that "Ultrez 10" was a carbomer polymer according to the definition in claim 1. Consequently, there was no experimental evidence that the claimed compositions effectively solved the alleged technical problem.

However, claim 1 is directed to antimicrobial compositions containing a combination of specific components, the effect to be achieved by the composition not being a technical feature of the claim. The question of whether these compositions show particular properties or not is thus not a question of insufficiency of disclosure, but is rather relating to the discussion of inventive step. Consequently, this argument cannot succeed.

2.4 The Appellant stated that in order to achieve a viscosity of greater than 5000 centipoise as required by claim 1 the carbomer polymer had to be used in an efficient amount, which in claim 8 is further specified as being from 0.2 to 2.0 weight percent. In the test reported in document (10) four compositions according to claim 1 of the patent in suit had been prepared. However, only composition 3, which used "Ultrez 10" in an amount of 0.7 weight percent showed a viscosity of

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greater than 5000 centipoise. Therefore, it was not possible to prepare the claimed compositions within the whole range claimed. The skilled person could prepare compositions falling within the definition of claim 1, which required a specific viscosity, only by excessive experimentation, which represented an undue burden.

However, those compositions described in document (10), which have viscosities of below 5000 centipoise do not fall within the definition of claim 1 and are thus not part of the invention. Further, these reworked examples were prepared with one particular carbomer polymer, namely "Ultrez 10". Other carbomer polymers falling within the definition of claim 1 might yield the required viscosity already in amounts below 0.7 weight percent.

Therefore, the Board is satisfied that the invention is disclosed in a manner sufficiently clear and complete for it to be carried out by a skilled person.

Consequently, the objection of the Appellant under Article 100 (b) EPC cannot succeed.

- 3. Novelty (Article 54 EPC)
- 3.1 The Appellant objected to the finding of the Opposition Division that the subject-matter of claim 1 was novel in view of documents (7) and (8). In particular, he submitted that "Carbopol 940", which was used in the prior art according to documents (7) and (8) was a carbomer polymer falling within the claims of the patent in suit. Consequently, the hairstyling cream RZ 9.258 of document (7), which comprised inter alia 50 percent of ethanol, 0,2 percent of "Dehyquart C", a

quaternary ammonium salt and 0.8 percent of "Carbopol 940", anticipated the subject-matter of claim 1 of the patent in suit. An analogous composition was disclosed in document (8) as the hairstyling gel composition WF 11-07.

3.2 This argumentation of the Appellant is based on the assumption that "Carbopol 940" was a carbomer polymer falling within the specific definition in claim 1.

However, the Appellant, who bears the onus of proof in this respect (T 182/89, OJ EPO 1991, 391), has neither substantiated this assumption, nor has he provided any corroborating evidence that "Carbopol 940" was a carbomer polymer falling within the definition of the specific carbomer polymer of claim 1. Therefore, the Appellant-Opponent's allegations are regarded as mere speculations, which the Board cannot adopt as a basis for its decision.

Consequently, the Board accepts that the subject-matter according to claim 1 is novel in view of documents (7) and (8).

- 4. Inventive step (Article 56 EPC)
- 4.1 The patent in suit is directed to an alcohol-based antimicrobial composition with cosmetic appearance that possesses the moisturizing attributes of a hand cream and lotion. Such compositions are already known from document (9a). The Opposition Division in the decision under appeal and both parties conceded that this document represents the closest state of the art and the Board sees no reason to depart from this finding.

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- Document (9a) discloses in Example 4 a composition comprising 75ml ethanol, 0.1 g benzalkonium chloride and 0.5 g "Highbis Wako (R) 105", which is a carboxyvinyl (= acrylic acid) polymer with a molecular weight of about 100 000. The composition forms a very good gel and is, thus, suitable as hand cream or lotion. Further, it has a sterilizing effect and has a smoothing effect on skin (Paragraph [0018] and [0019] and Table 1).
- 4.3 Having regard to this prior art document, the
  Respondent submitted that the technical problem
  underlying the patent in suit was to provide an
  alternative to the antimicrobial composition disclosed
  in Example 4 of document (9a).
- As solution to this problem the patent in suit proposes the composition according to claim 1, which is characterised by the fact that it uses a specifically modified carbomer polymer instead of the "Highbis Wako (R) 105" polymer and that the viscosity of the composition is adjusted to values greater than 5000 centipoise.
- 4.5 To support that the solution proposed by the patent in suit successfully solves the technical problem mentioned above (Paragraph 4.3 supra) the Respondent referred to the examples of the patent specification. In view of these examples the Board considers that the claimed compositions represent alternatives to the compositions known from the prior art.
- 4.6 It remains to be decided whether or not the proposed solution to the objective technical problem mentioned

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above (see paragraph 4.3 *supra*) is obvious in view of the state of the art.

4.7 The skilled person, when looking for an alternative composition, will consider to use alternative components having similar structure and similar properties. The thickener used in document (9a), "Highbis Wako (R) 105", is an acrylic homopolymer. Therefore, when looking for an alternative composition the skilled man will consider other known acrylic thickeners in replacement of "Highbis Wako (R) 105".

Document (11), which is a brochure on Carbopol polymers for thickening, suspending and stabilising, describes various acrylic homopolymers or acrylic copolymers, which are suitable as thickeners in creams, gels and lotions. The most preferred one is the "Ultrez 10" polymer, i.e. a polymer falling within the definition of claim 1 (see paragraph [0017] of the patent specification). This polymer is described as showing easy dispersing properties and all the performance properties known from other acrylic polymers, such as the "Carbopol" polymers. Therefore, when looking for an alternative composition the skilled person gets from document (11) the clear indication to use "Ultrez 10" as an alternative acrylic polymer.

The composition of example 4 of the closest prior art document (9a) forms a very good gel, which makes it suitable as hand cream or lotion (see paragraph 4.2 supra). Therefore, although not expressly mentioned, this composition might have a viscosity of greater than 5000 centipoise, in particular, since the viscosity value of 5000 centipoise is rather low and relates to

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rather fluid gels. Thus, the selection of particular viscosity values of greater than 5000 centipoise in the patent in suit is regarded as being an arbitrary threshold, which cannot support any inventive activity.

4.7.1 The Respondent argued that document (11) disclosed that "Ultrez 10" had a low relative ion tolerance. Therefore, the skilled person would not have considered to use "Ultrez 10" in combination with ionic compounds, such as benzalkonium chloride, while keeping the viscosity in the desired range.

However, a low ion tolerance is not to be understood as an absolute incompatibility with ionic components.

Minor amounts, such as 0.2 g of benzalkonium chloride in example 4 of document (9a) may be present.

Therefore, the skilled person would not be deterred from using "Ultrez 10", but would follow the clear teaching in document (11) to use "Ultrez 10" as alternative compound.

4.7.2 The Respondent submitted that the skilled person had no incentive at all to modify the compositions disclosed in document (9a).

However, in order to solve the technical problem underlying the present invention, which was solely to provide alternative compositions, a skilled person always has to modify the teaching of the closest prior art.

4.8 For these reasons, the Board concludes that the subject-matter of claim 1 is obvious in the light of documents (9a) and (11).

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## Auxiliary requests I and II

- 5. Amendments (Article 123 EPC)
- 5.1 Claim 1 of the auxiliary request I was based on the wording of granted claim 1, wherein the "cationic antimicrobial compound" was further specified as being "benzalkonium chloride, methyl benzethonium chloride or cetyl pyridinium chloride", which is based on original claim 4 and restricts the scope of protection conferred by granted claim 1.
- 5.2 Claim 1 of the auxiliary request II was based on the wording of granted claim 1, which was further restricted by appending the feature "wherein the total cationic compound level is from 0.05 to 0.5% by weight" to the end of claim 1. A basis for this amendment is to be found on page 4, lines 7 to 9 of the application documents. The amendment restricts the scope of protection conferred by claim 1 as granted.
- 5.3 Therefore, the Board is satisfied that the amendments made to the claims of the auxiliary requests I and II fulfil the requirements of Article 123(2) and (3) EPC.
- 6. As novelty was acknowledged for the subject-matter of the broader claim 1 of the main request, the same argumentation and considerations for novelty apply also to the subject-matter of claim 1 of auxiliary requests I and II.

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## 7. Inventive step (Article 56 EPC)

The argumentation on inventive step for the main request focussed already on example 4 of document (9a), which disclosed a composition comprising benzalkonium chloride as cationic antimicrobial compound in an amount of 0.2 percent. Therefore, the restrictions introduced into claim 1 of auxiliary requests I and II, which specify the cationic antimicrobial compound as being inter alia benzalkonium chloride and which specifiy the total cationic compound level to 0.05 to 0.5 percent by weight, do not alter the argumentation for inventive step as brought forward already for the main request. Therefore, the same argumentation and considerations as set out already for the discussion of inventive step of the main request apply also to the subject-matter of claim 1 of auxiliary requests I and II. Consequently, the Board comes to the conclusion that the subject-matter of claim 1 of auxiliary requests I and II does not involve an inventive step in the sense of Article 56 EPC for the same reasons as set out for the main request.

## Auxiliary request III

## 8. Amendments (Article 123(2) and (3) EPC)

Claim 1 of the auxiliary request III was based on the wording of claim 1 of granted claim 1, wherein the "cationic antimicrobial compound" was further specified as being "benzalkonium chloride, methyl benzethonium chloride or cetyl pyridinium chloride", the presence of "cetyl lactate from 0.3 to 1.5 weight percent and  $C_{12}$ - $C_{15}$  alkyl lactates from 0.2 to 2.0 weight percent" was

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claimed and "wherein the total cationic compound level is from 0.05 to 0.5% by weight". Basis for the amendments is to be found in original claims 4 and 7 and on page 4, lines 7 to 9 of the application documents. The amendments restrict the scope of protection conferred by claim 1 as granted.

Therefore, the Board is satisfied that the amendments made to claim 1 of the auxiliary requests III fulfil the requirements of Article 123(2) and (3) EPC.

- 9. The restrictions made to claim 1 consist in a further specification of a particular group of compounds by individually cited and known components, and by incorporation of additional additives in specified amounts into claim 1 (see paragraph 8. supra). These amendments do not introduce any insufficiently disclosed matter into claim 1. As novelty and sufficiency of disclosure were acknowledged for the subject-matter of the broader claim 1 of the main request, the same argumentation and considerations for novelty and for sufficiency of disclosure apply also to the subject-matter of claim 1 of auxiliary request III.
- 10. Inventive step (Article 56 EPC)
- 10.1 In agreement with both parties to the appeal the closest state of the art and the technical problem underlying the subject-matter of claim 1 remained the same as for the previous requests (see paragraphs 4.1 to 4.3 and 7. supra).
- 10.2 As solution to the technical problem the patent in suit proposes the composition according to claim 1, which is

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characterised by the fact that it uses a specifically modified carbomer polymer instead of the "Highbis Wako (R) 105" polymer, that the viscosity of the composition is adjusted to values greater than 5000 centipoise and by the presence of cetyl lactate and  $C_{12}$ - $C_{15}$  alkyl lactates in specified amounts.

- 10.3 As the proposed solution credibly provides alternative compositions the Board is satisfied that the solution is successful (see paragraph 4.5 supra). This was not disputed among the parties.
- 10.4 Finally, it remains to be decided whether or not the proposed solution to the technical problem as identified in paragraph 10.2 *supra* is obvious in view of the state of the art.
- None of the cited documents mentions the presence of cetyl lactate and  $C_{12}$ - $C_{15}$  alkyl lactates, let alone in the specific amounts claimed. Further, none of the cited documents provides the information that the incorporation of these compounds does not deteriorate the overall properties of the claimed composition. Consequently, a skilled person would not have considered to use these particular components in the specific amounts as claimed when looking for an alternative to the compositions known from the prior art as disclosed in document (9a).
- 10.6 The Appellant brought forward that cetyl lactate and  $C_{12}$ - $C_{15}$  alkyl lactates were conventional additives. To incorporate these compounds in addition to the other components of the composition was within the routine of

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a skilled person and does not require any inventive ingenuity.

However, there is no evidence that cetyl lactate and  $C_{12}$ - $C_{15}$  alkyl lactates were known as conventional additives in the particular technical field of the present invention, i.e. antimicrobial compositions. Even if they were regarded as conventional additives there is still no indication in the prior art that these components, when combined with the other ingredients required by claim 1 do not adversely affect the properties of the claimed compositions.

10.7 For these reasons the Board concludes that the subject-matter of claim 1 according to auxiliary request III, and that of the dependent claims 2 to 6, which contains all technical features of claim 1, involves an inventive step within the meaning of Article 56 EPC.

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## 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 an order to maintain the patent on the basis of claims 1 to 6 filed as auxiliary Request III with letter dated 18 September 2008, and a description yet to be adapted.

The Registrar

The Chairman

A. Counillon

P. Gryczka