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Datasheet for the decision of 23 May 2023

Case Number: T 0592/19 - 3.3.02

Application Number: 09771560.1

Publication Number: 2512231

IPC: A01N25/04, A61K8/34, A61K31/045, A01P1/00

Language of the proceedings: EN

Title of invention:
COMPOSITION IN FORM OF A GEL FOR THE VIRUCIDAL DISINFECTION OF MAMMALIAN SKIN

Patent Proprietor:
ECOLAB INC.

Opponents:
L'Air Liquide, Société Anonyme pour l'Etude et l'Exploitation des Procédés Georges Claude/FR
Schülke & Mayr GmbH/DE
Bode Chemie GmbH

Headword:

Relevant legal provisions:
EPC Art. 83, 100(a)
RPBA 2020 Art. 11

Keyword:
Sufficiency of disclosure
Remittal to the department of first instance
Remittal - (yes)

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

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Case Number: T 0592/19 - 3.3.02

D E C I S I O N
of Technical Board of Appeal 3.3.02
of 23 May 2023

Appellant: (Patent Proprietor)	ECOLAB INC. 370 N Wabasha Street St. Paul, MN 55102 (US)
Representative:	Godemeyer Blum Lenze Patentanwälte Partnerschaft mbB - werkpatent An den Gärten 7 51491 Overath (DE)
Respondent: (Opponent 1)	L'Air Liquide, Société Anonyme pour l'Etude et l'Exploitation des Procédés Georges Claude/FR Schülke & Mayr GmbH/DE 75, quai d'Orsay/FR Robert-Koch-Strasse 2/DE 75007 Paris/22851 Norderstedt (FR)
Representative:	LKGLOBAL Lorenz & Kopf Patentanwalt Attorney at Law PartG mbB Brienner Straße 11 80333 München (DE)
Respondent: (Opponent 2)	Bode Chemie GmbH Melanchthonstrasse 27 22525 Hamburg (DE)
Representative:	Ter Meer Steinmeister & Partner Patentanwälte mbB Nymphenburger Straße 4 80335 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 21 December 2018 revoking European patent No. 2512231 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	M. O. Müller
Members:	P. O'Sullivan
	I. Beckedorf

Summary of Facts and Submissions

I. The appeal of the patent proprietor (hereinafter appellant) lies from the decision of the opposition division according to which European patent 2 512 231 was revoked for lack of sufficient disclosure.

The contested decision was based on the patent as granted as main request and sets of claims of first to sixth auxiliary requests.

II. The following documents *inter alia* were submitted by the parties in opposition proceedings:

D6 Lubrizol technical data sheet TDS-237, dated 16 September 2009;
D7 Lubrizol technical data sheet TDS-255, dated 3 September 2009;
D11 EP 1 281 319 A1

III. In preparation for oral proceedings, scheduled according to the parties' requests, the board issued a communication pursuant to Article 15(1) RPBA 2020. Therein, the board expressed the preliminary view that the ground for opposition under Article 100(b) EPC did not prejudice maintenance of the patent as granted.

IV. Oral proceedings before the board took place as scheduled on 23 May 2023 in the presence of the appellant and both respondents 1 and 2.

V. Requests

The appellant requested that the contested decision be set aside, and that the invention be found to be

sufficiently disclosed on the basis of the main request (patent as granted) or on the basis of any of the sets of claims of the first to sixth auxiliary requests filed with the statement of grounds of appeal.

The appellant further requested that the case be remitted to the opposition division for further prosecution.

Opponents 1 and 2 (hereinafter respondents 1 and 2) requested that the appeal be dismissed.

Furthermore, respondent 1 agreed with the appellant's request to remit the case to the opposition division for further prosecution, in the event that one of the appellant's requests was found to be sufficiently disclosed.

Respondent 2 also requested remittal of the case to the opposition division for further prosecution should sufficiency of disclosure be acknowledged for one of the appellant's requests.

VI. For the text of claim 1 of the main request, reference is made to the reasons for the decision, below.

VII. For the parties' submissions relevant to the present decision, reference is made to the reasons for the decision provided below.

Reasons for the Decision

Main request (patent as granted)

1. Article 100(b) EPC - sufficiency of disclosure

1.1 The contested patent concerns a virucidal alcoholic gel composition having a viscosity within a certain range, thereby providing for sufficient inactivation of the virus concerned (see patent, e.g. paragraphs [0023] and [0024]).

Granted claim 1 reads as follows:

"*Composition in form of a gel for the virucidal disinfection of mammalian skin comprising*
85 to 95 wt-% of ethanol,
0,01 to 1 wt-% thickener, and
wherein the composition has a viscosity range of from 5000 to 9000 mPas measured at 20°C with spindle LV3 at a speed of 2.5 rpm."

1.2 The contested decision

1.2.1 According to the contested decision, the relevant question for sufficiency of disclosure was whether the gel compositions of claim 1 having a thickener concentration and viscosity within the claimed ranges could be reproduced by the skilled person without undue burden. The requirement of "undue burden" was not met when the skilled person could only establish by trial and error whether or not a particular choice of thickener was capable of providing the claimed composition (page 7, point 3.1, second paragraph, and page 8, third paragraph).

1.2.2 The opposition division reasoned that "working within the range of claim 1 does not necessarily result in a gel having the required viscosity" (decision, point 3.1, third and fourth paragraphs). Furthermore, the skilled person, having determined whether a given thickener was suitable or not for obtaining the claimed viscosity, was still not in possession of any guidance to select further thickeners (i.e. additional thickeners which could be used to prepare a composition according to contested claim 1). Hence, the skilled person would need to establish by trial and error for virtually every thickener, whether and at which concentration it provided the claimed gel viscosity. The large number of experiments required amounted to an undue burden for the skilled person. Hence, contested claim 1 was not sufficiently disclosed.

1.3 The appellant with the statement of grounds of appeal argued that the opposition division's decision was incorrect.

1.4 Respondent's 1 and 2 in their respective replies to the statement of grounds of appeal largely followed the line of reasoning provided by the opposition division. Further arguments submitted by the respondents in appeal proceedings are addressed below.

1.5 The board's view

1.5.1 Claim 1 requires that the claimed composition comprises 85 to 95 wt-% ethanol and a thickener, wherein the thickener

- is present in an amount of 0.01 to 1% wt-%, and
- results in a composition with a viscosity of 5000 to 9000 mPa.

1.5.2 The thickener is defined functionally to provide the claimed viscosity when present within the claimed amount range. It follows that for the invention defined in claim 1 to be sufficiently disclosed, the skilled person, using the information in the patent and the common general knowledge, must be able to prepare such a composition without undue burden.

1.5.3 This means that the skilled person must be able to select suitable thickeners which will provide a composition having a viscosity within the range of claim 1, when present within the claimed amount range.

1.5.4 The patent provides information regarding the types of thickeners that can be used (paragraphs [0032] and [0033]). The examples, although silent with regard to the specific thickener employed, show that the preparation of a composition displaying the features of claim 1 was achieved (examples 1 and 3).

1.5.5 As noted by the appellant, the invention underlying the present patent relates to an alcoholic gel for the virucidal disinfection of mammalian skin, wherein the composition has a viscosity within the specific range of claim 1, therewith providing sufficient inactivation of test viruses (e.g. patent, paragraph [0012]). Hence, the invention is not directed to the use of specific thickeners for virucidal disinfection, but to alcoholic gels for the virucidal disinfection of mammalian skin.

1.5.6 Furthermore, it was not disputed by the respondents that gel-like compositions comprising alcohol for disinfection purposes were already known from the state of the art. For example, the patent (paragraph [0015]) refers to prior art patent document D11, which

discloses an alcoholic gel comprising a thickener for the disinfection of hands (paragraph [0001]).

1.5.7 The board agrees with the appellant that in the absence of any evidence to the contrary, the preparation of a composition according to claim 1 comprising an appropriate thickener is a routine matter: it is not *prima facie* a complex undertaking. Indeed, it would be a simple matter to determine whether a given thickener would be appropriate for preparing a composition according to claim 1. Specifically, a simple test could be performed whereby a composition comprising an amount of ethanol within the claimed range could be tested both with 0.01 wt% and with 1.0 wt% of a given thickener, i.e. at the lower and upper limits of the amount provided in claim 1. If either the viscosity at the lower amount in wt% were higher than the claimed viscosity range, or the viscosity at the higher amount in wt% were below the claimed viscosity range, then the skilled person would conclude that said thickener was not appropriate for preparing a composition according to contested claim 1. In all other cases, the amount of thickener required to arrive at a composition having a viscosity within the range stipulated in claim 1 could routinely be calibrated by adjusting the given thickener amount from between 0.01 and 1.0 wt% until a viscosity within said range were obtained. The skilled person would know that if the viscosity for a given amount of thickener were too high, it could be reduced by reducing the amount of said thickener, and vice versa. Hence, each test would provide the direction, in terms of either raising or lowering the amount of thickener, that should be implemented for the subsequent test, with a view to arriving within the claimed viscosity range.

1.5.8 Hence, the board sees no reason why preparing a composition according to claim 1 would involve anything more than routine experimentation for the skilled person.

1.6 The respondents' further arguments to the contrary failed to convince the board, as detailed in the following.

1.6.1 In line with the conclusions of the opposition division (contested decision, page 9, penultimate paragraph - page 10, second full paragraph), the respondents argued that for claim 1 to be sufficiently disclosed, it must be possible for the skilled person to carry it out across the whole area claimed without undue burden. Even if the skilled person were, by trial and error, to determine the concentration of a given thickener necessary to provide the viscosity stipulated in claim 1, this information would be of no use in evaluating whether **further** thickeners could provide the required viscosity within the claimed ranges. Hence, the skilled person would need to test each and every thickener to see whether it was suitable, and if so, at which concentration. Due to the large number of experiments required, this would amount to an undue burden.

The board does not agree. For sufficiency of disclosure to be acknowledged, it is enough that the skilled person is capable of finding appropriate thickeners which fulfill the concentration and viscosity requirements of claim 1. It is not necessary for the skilled person to test all thickeners. Rather, as stated above, the invention concerns a virucidal composition. In order for this composition to be sufficiently disclosed, the skilled person must be able to prepare a composition as claimed. To do this, the

skilled person must simply be capable of determining whether a given thickener is suitable for providing the claimed viscosity within the claimed concentration range. As noted above, this can be determined by routine experimentation and thus without undue burden, and there is no indication nor evidence to the contrary. Indeed, the respondents have not submitted evidence of a single specific thickener for which the preparation of a composition according to claim 1 would not be possible.

1.6.2 A further argument of the respondents was that the examples of the patent did not disclose the specific thickener employed and therefore failed to demonstrate one way of carrying out the invention, therefore implying that claim 1 was insufficiently disclosed.

It was not disputed by the appellant that the examples of the patent do not disclose the specific thickener employed. The board notes however that it is not a prerequisite of sufficiency of disclosure that one specific way of carrying out the invention, in terms of a concrete example, is required. Rather, the only requirement is that the skilled person, given the information in the patent as a whole in combination with the common general knowledge, is capable of putting the invention into practice. Indeed, the presence of examples in the patent is not a mandatory requirement of the EPC.

Nevertheless, the board agrees with the appellant that the skilled person would understand from the use of a tetrahydroxypropylethylendiamine as the neutralizer in the examples of the patent (table 1, lines 49-50) that the thickener used must be a polyacrylic acid or copolymer of polyacrylic acid, for which a neutralizer

is required according to paragraph [0033] of the patent. Therefore, on the basis of the examples, the skilled person would learn of at least one specific class of thickeners from which a choice could be made.

1.6.3 The respondents also argued that specific thickeners falling within the general terms of those mentioned in paragraph [0032] of the patent and allegedly employed according to the examples, were not referenced in the patent, and were not part of the common general knowledge of the skilled person. In particular, although inter alia patent document D11 and technical data sheets D6 and D7 all concerned the formulation of hydroalcoholic gels with such thickeners, none represented handbooks, textbooks or reference books, and thus did not constitute common general knowledge.

Paragraph [0032] of the patent refers to the preferred thickeners, namely polyacrylic acid, a polyacrylate, a copolymer of a polyacrylic acid and a polyacrylic acid alkyl ester, a copolymer of a polyacrylate and a polyacrylic acid alkyl ester.

As noted by the appellant, at least D11, which describes a specific polyacrylic acid thickener according to paragraph [0032] of the patent, is mentioned in the patent (paragraph [0015]) and would thus serve as relevant information to the skilled person regarding said thickeners.

The board disagrees with the respondents that D11 may not be taken as evidence of the common general knowledge. Specifically, the skilled person wishing to carry out the invention, if necessary, would look to the prior art cited in the patent for guidance, in

particular since the presence of a thickener is central to the invention.

D11 both provides information concerning the specific polyacrylic acid thickening system, and, as noted by the appellant, the fact that the amount of thickener required will depend on the type of thickener employed, and the alcohol concentration in the composition (D11, paragraph [0017]). It discloses that alcoholic gels are known, and are normally thickened with polyacrylic acids (paragraph [0002]). "Carbopol" polymers are provided in the table on page 2 as examples of such polyacrylic acids. A further table on page 3 of D11 (paragraph [0014]) provides an overview of the state of the art, much of which employs polyacrylic acids as the thickener (table, column entitled "Verdicker").

Hence, D11 demonstrates that the use of polyacrylic acid thickeners was common general knowledge before the priority date of the application.

The board also agrees with the appellant that at least technical data sheets D6 and D7, both dated before the priority date of the patent, represent evidence of the common general knowledge on the basis that such thickening methods had not yet made their way into textbooks or monographs.

These data sheets disclose that Carbopol polymers were typically used in conjunction with a neutraliser to thicken alcoholic solutions (e.g. D6, title, and page 1-2; D7, title and page 2, "Polymer Selection").

Consequently, the board is satisfied that the class of thickeners mentioned in paragraph [0032] of the patent was part of the common general knowledge of the skilled

person at the priority date of the patent. Hence, preparing the claimed compositions using these thickeners would not have involved an undue burden for the skilled person.

1.6.4 In the same context, respondent 2 argued that the skilled person wishing to prepare a composition according to the examples of the patent would be faced with undue burden in choosing a concrete thickener. Firstly, D7 (e.g. page 3, bottom figure) provided evidence that thickening properties varied widely, even within the same class of thickeners. Secondly, the compositions of the examples all comprised further "skin care ingredients and emollients" (patent, table 1, fourth row), which also had an effect on the viscosity, and the nature of which was not specified and therefore unknown. There was also no further information in the patent in this regard.

The board however notes that even if the examples of the patent cannot be reproduced exactly due to certain missing information as identified by the respondent, this does not equate with a conclusion that the invention cannot be carried out by the skilled person. Specifically, the ability to exactly rework the examples of the patent is not a prerequisite for sufficiency of disclosure to be acknowledged. Again, the skilled person, using the information in the patent and common general knowledge, must be able to prepare a composition falling within the scope of claim 1 without undue burden. As set out above, the determination of whether any specific thickeners would be suitable for providing the claimed composition (i.e. providing the claimed viscosity when present in the claimed amount) is not a complex undertaking and can be performed by

routine experimentation. Furthermore, no evidence was submitted casting a doubt on this view.

1.6.5 It was additionally argued by the respondents that "the claimed amount of thickener did not necessarily lead to the desired viscosity", citing example 2 and comparative example 4 of the patent (table 1, page 5) as evidence. Hence, the claimed subject-matter was not sufficiently disclosed.

Example 2 of the patent discloses a composition comprising 0.2740 wt% of a thickener system, providing a viscosity of 9900 MPa, while comparative example 4 discloses a composition comprising 0.3650 wt% of the thickener system and a viscosity of 20250 MPa. Hence, although the amount of thickener of both examples lies within the claimed range, the viscosity reading lies outside the claimed range.

As argued by the appellant, claim 1 sets out two criteria for the thickener in the composition, namely that it be present in a specific amount, and that within that specific amount range, a viscosity within a specific range is obtained. Hence, example 2 and comparative example 4 do not fall within the scope of claim 1. However, the board fails to see how these examples serve as evidence that the skilled person would be unable to provide the claimed composition. Indeed, in examples 1 and 3, compositions meeting the requirements of claim 1 are in fact provided, and as set out above, identifying a suitable thickener and a suitable amount thereof to provide a composition according to claim 1 involves only routine experimentation.

1.6.6 In the same context it was argued that a very minor difference in the amount of thickener system used in example 1 versus example 3 of the patent (0.230 wt% versus 0.2190 wt%) led to a large difference in viscosity (8200 versus 5900 MPa). This demonstrated that it was not straightforward to select the amount of thickener required to achieve a viscosity within the claimed range. Hence, the skilled person was faced with undue burden in providing the claimed compositions.

The board agrees with the respondent's observation in relation to examples 1 and 3 of the patent, in particular that the data demonstrates that for these examples, a minor change in the amount of thickener leads to a relatively large change in viscosity. However, even accepting this, the board sees no reason why the skilled person would be unable to determine the amount of thickener required to arrive within the claimed viscosity range by routine experimentation, as set out above. Furthermore, even if the skilled person were to initially fail to prepare a composition according to claim 1 using a specific thickener, a further thickener could be tested. Again, there is no evidence that identifying a thickener suitable for preparing a composition according to claim 1 would amount to undue burden for the skilled person.

1.6.7 In a further related argument, respondent 2 in particular submitted that D7 (page 4, table, penultimate entry) only taught the use of ethanol up to a maximum concentration of 90%, which was below the claimed upper value of 95%. Hence, claim 1 was not sufficiently disclosed for compositions comprising more than 90% ethanol.

The board disagrees. As stated by the appellant, table 4 of D7 provides a set of recommendations, but does not serve as evidence that the claimed composition cannot be prepared at alcohol concentrations above 90%. The respondent's submission therefore amounts to no more than an unsubstantiated allegation, and fails at least for that reason.

1.7 Finally, respondent 2 argued that the burden of proof that the invention defined in contested claim 1 was sufficiently disclosed lay with the appellant. Specifically, the respondent referred to established case law according to which, when a patent does not give any information as to how a feature of the invention can be put into practice, only a weak presumption exists that the invention is sufficiently disclosed. In such a case, the opponent can discharge its burden in proving insufficiency of disclosure by plausibly arguing that the common general knowledge would not enable the skilled person to put the claim into practice.

As set out above however, the board does not share the view that the skilled person would be unable to put the invention into practice on the basis of the information in the patent and the common general knowledge. In short, there is no reason to doubt that it would be routine for the skilled person to choose an appropriate thickener which, when present in the composition in an amount within the claimed weight range, would provide a viscosity within the claimed range.

Consequently, the burden of proof in the present situation rests with the respondents, and has not been discharged.

It follows that given the absence of any evidence to the contrary, the invention defined in claim 1 is disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

1.8 In view of the foregoing, the ground for opposition under Article 100(b) EPC does not prejudice the maintenance of the patent as granted.

2. Remittal - Article 11 RPBA 2020

The appellant requested that should sufficiency of disclosure be acknowledged, the case be remitted to the opposition division for further prosecution.

Both respondents agreed with the appellant's request.

According to Article 11 RPBA 2020, the board shall not remit a case to the department whose decision was appealed for further prosecution, unless special reasons present themselves for doing so.

In the present case, the grounds for opposition under Article 100(a) EPC (novelty and inventive step) were neither addressed in the contested decision, nor in the parties' submissions in appeal. Hence, there is nothing on the basis of which the board can assess these grounds in appeal proceedings in the sense of Articles 12(1) and (2) RPBA 2020. In the view of the board, this constitutes a special reason in the sense of Article 11 RPBA 2020.

Furthermore, both the appellant and the respondents either requested or agreed that the case be remitted to the opposition division for further prosecution.

For these reasons, and in line with the parties' requests, the board decided to remit the case to the opposition division for further prosecution.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the opposition division for further prosecution.

The Registrar: The Chairman:

N. Maslin M. O. Müller

Decision electronically authenticated