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Datasheet for the decision
of 24 January 2019

Case Number: T 1704/16 - 3.3.07

Application Number: 07121381.3

Publication Number: 1935395

IPC: A61Q11/00, A61K8/81, A61K8/02

Language of the proceedings: EN

Title of invention:
Oral composition

Patent Proprietors:
Unilever PLC
Unilever N.V.

Opponent:
Colgate-Palmolive Company

Headword:
Oral composition/Unilever PLC and Unilever N.V.

Relevant legal provisions:
EPC Art. 100(b), 123(3)
RPBA Art. 13(1)
Keyword:
Main request - Sufficiency of disclosure (No)
Auxiliary requests 1-3 - Admission into the proceedings (No)
Auxiliary request 4 - Admission into the proceedings (Yes)
Auxiliary request 4 - Extension of the scope of protection

Decisions cited:

Catchword:
Decision of Technical Board of Appeal 3.3.07 of 24 January 2019

Appellant: Colgate-Palmolive Company
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Decision under appeal: Decision of the Opposition Division of the European Patent Office posted on 19 May 2016 rejecting the opposition filed against European patent No. 1935395 pursuant to Article 101(2) EPC.
Composition of the Board:

Chairman: J. Riolo
Members: D. Boulois
         P. Schmitz
Summary of Facts and Submissions

I. European patent No. 1 935 395 was granted on the basis of a set of 10 claims.

Independent claim 1 as granted read as follows:

"1. An oral care composition comprising from 0.01 to 0.3% by weight of a pigment having a hue angle, h, in the CIELAB system of from 220 to 320 degrees, characterized in that the composition further comprises a water soluble deposition aid for said pigment that is a polymer having a molecular weight of 200,000 or greater, is not a film-forming polymer and is selected from co-polymers of maleic anhydride with methyl vinyl ether, in which the anhydride moiety may be in a partially or fully hydrolysed or alcoholysed form."

II. An opposition was filed under Article 100 (a), (b) and (c) EPC on the grounds that the subject-matter of the granted patent lacked novelty and inventive step, was not sufficiently disclosed, and extended beyond the content of the application as filed.

III. The appeal lies from the decision of the opposition division to reject the opposition. The decision was based on the claims as granted.

IV. The documents cited during the opposition proceedings included the following:
D12: Personal Care Reference Guide, International Speciality Products, 2009 (not part of the state of the art)
V. According to the decision under appeal, as regards sufficiency of disclosure, the opposition division considered that the claimed invention was sufficiently disclosed, with regard to the term "not a film-forming polymer" used in claim 1 as granted. According to the opposition division, the skilled person reading the specification would not have considered that the Gantrez polymers used therein did not fall under the definition given in claim 1 as "not a film-forming polymer" and would have been able to obtain substantially all embodiments falling within the ambit of the claims. The suitability of the Gantrez polymers was demonstrated by the experimental section of the specification.

In view of D14, the opposition division considered in particular that the film-forming properties of the Gantrez polymers were dependent on the reaction conditions and that said polymers did not automatically form a film in any situation. It was clear from the description and from D13/D14 that the film-forming properties of the polymers per se depended on the conditions under which they were used. Moreover, in the context of the claimed invention, in particular of paragraph [0015] of the specification, the term "not a film-forming polymer" could only mean that the polymers to be used should not form a film on the teeth, and not build up on the teeth.

Claim 1 was furthermore novel and inventive over the prior art and met the requirements of Article 123(2) EPC.
VI. The opponent (hereinafter the appellant) filed an appeal against said decision.

VII. In its reply to the statement of grounds of appeal, the patent proprietors (hereinafter the respondents) filed a main request, corresponding to the claims as granted, and auxiliary requests 1 to 4.

VIII. A communication from the Board, dated 26 October 2018, was sent to the parties. In this it was considered in particular that the claimed invention did not appear to be sufficiently disclosed, in view of the term "not a film-forming polymer" present in claim 1.

IX. With a letter dated 18 December 2018, the respondent filed new auxiliary requests 1 to 4. Said letter also comprised the results of an experimental test.

The subject-matter of the independent claims 1 of the auxiliary requests read as follows, the difference(s) compared with the main request (i.e. the patent as granted) shown in bold:

**Auxiliary request 1**

"1. An oral care composition comprising from 0.01 to 0.3% by weight of a pigment having a hue angle, h, in the CIELAB system of from 220 to 320 degrees, characterized in that the composition further comprises a water soluble deposition aid for said pigment that is a polymer having a molecular weight of 200,000 or greater, is not a film-forming polymer and remains water-soluble following drying and is selected from co-polymers of maleic anhydride with methyl vinyl ether,
in which the anhydride moiety may be in a partially or fully hydrolysed or alcoholysed form."

Auxiliary request 2

"1. An oral care composition comprising from 0.01 to 0.3% by weight of a pigment having a hue angle, h, in the CIELAB system of from 220 to 320 degrees, characterized in that the composition further comprises a water soluble deposition aid for said pigment that is a polymer having a molecular weight of 200,000 or greater, is not a film-forming polymer and is selected from co-polymers of maleic anhydride with methyl vinyl ether, in which the anhydride moiety may be in a partially or fully hydrolysed or alcoholysed form, wherein the polymer has a molecular weight 216,000 free acid; has a molecular weight 700,000, free acid; has a molecular weight 1,500,000, free acid; or has a molecular weight 1,060,000, calcium/sodium salt."

Auxiliary request 3

"1. An oral care composition comprising from 0.01 to 0.3% by weight of a pigment having a hue angle, h, in the CIELAB system of from 220 to 320 degrees, characterized in that the composition further comprises a water soluble deposition aid for said pigment that is a polymer having a molecular weight of 200,000 or greater, is not a film-forming polymer and remains water-soluble following drying and is selected from co-polymers of maleic anhydride with methyl vinyl ether, in which the anhydride moiety may be in a partially or fully hydrolysed or alcoholysed form, wherein the polymer has a molecular weight 216,000 free acid; has a molecular weight 700,000, free acid; has a molecular
weight 1,500,000, free acid; or has a molecular weight
1,060,000, calcium/sodium salt."

Auxiliary request 4

"1. An oral care composition comprising from 0.01 to
0.3% by weight of a pigment having a hue angle, h, in
the CIELAB system of from 220 to 320 degrees,
characterized in that the composition further comprises
a water soluble deposition aid for said pigment that is
a polymer having a molecular weight of 200,000 or
greater, is not a film-forming polymer and is selected
from co-polymers of maleic anhydride with methyl vinyl
ether, in which the anhydride moiety may be in a
partially or fully hydrolysed or alcoholysed form,
selected from Gantrez S-95 (molecular weight 216,000
free acid), Gantrez S-96 (molecular weight 700,000,
free acid), Gantrez S-97 (molecular weight 1,500,000,
free acid) and Gantrez MS-955 (molecular weight
1,060,000, calcium/sodium salt)."

X. With a letter dated 21 December 2018, the appellant
requested that the auxiliary requests not be admitted
into the proceedings.

XI. Oral proceedings took place on 24 January 2019.

XII. The arguments of the appellant may be summarised as
follows:

Main request - Sufficiency of disclosure

The claimed invention was not sufficiently disclosed,
since it required a polymer that has the intrinsic
property that it is "not a film-forming polymer" while
the only disclosure of a polymer that is "selected from
co-polymers of maleic anhydride with methyl vinylether, in which the anhydride moiety may be in a partially or fully hydrolysed or alcoholised form", as additionally required by the polymer of the claimed invention, was of polymers that were film forming polymers, for example the Gantrez polymers disclosed in some of the Examples.

It was explicit from D12 and D13 that the copolymers Gantrez S had film-forming properties and it was implicit from D14 that the free-acid form of Gantrez AN had film forming properties; documents D10 and D11 confirmed that Gantrez polymers were used as film-forming polymers on the teeth. There was no enabling disclosure of a polymer that (i) had the recited chemical composition and (ii) had the recited physical property of not being a film former.

Claim 1 was clear by reciting that the polymer was "not a film-forming polymer", and thus it was not a problem of clarity.

As to the argument that the invention required that the polymer should be water-soluble to avoid build-up of the deposition aid on the teeth, claim 1 did not define the polymer of the invention by reciting the extrinsic property or to any contextual property of how the polymer was alleged to behave when applied to the teeth. It was clear that the recited invention defined an intrinsic property of the polymer, and not a property of the oral care composition, or how the polymer in the oral care composition behaved when the oral care composition was used. Moreover, it was clear from the explanation of the mechanism of action of the deposition aid given in paragraph [0020] of the "A" publication that a film was formed on the surface by the polymeric deposition aid.
The new evidence filed by the respondents in their letter of 18 December 2018 clearly showed that the respondents were trying to apply a subjective, ex post facto test for the disclosure and meaning of "film-forming" polymers which were not objectively derivable by the skilled person from the original specification and was not supported by datasheets such as D12-D14. Said experiments showed also implicitly that a film was applied to the tooth surfaces which was progressively removed by successive rinses.

Admission of auxiliary requests 1 to 4 into the proceedings

These requests should not be admitted, since none of auxiliary requests 1 to 3 could overcome the objection of sufficiency of disclosure and auxiliary request 4 was prima facie not allowable under Article 123(3) EPC.

Auxiliary request 4 – Article 123(3) EPC

All claimed Gantrez polymers were film-forming polymers, and the claimed subject-matter extended the protection conferred, since claim 1 as granted exclude all film-forming polymers.

XIII. The arguments of the respondents may be summarised as follows:

Main request – Sufficiency of disclosure

It was clear that the key phrase “not a film-forming polymer”, had to be understood that whether indeed a co-polymer is a “film-forming polymer” or not depended on the conditions in which the co-polymer was examined.
The ability of any such co-polymer to film-forming was clearly a contextual property. Although it was appreciated that the co-polymers described in the literature were variously referred to as being “film-forming”, it was clear that this property could at best be regarded as a generalisation of the co-polymer properties in what might be regarded as a typical use context. However, as document D14 pointed out, so-called “film-forming” Gantrez AN co-polymers, could not be regarded as "film-forming" polymer when used with certain solvents. It was safe to say that this document clearly suggested that Gantrez AN co-polymers cannot be regarded as universally “film-forming”.

This point was also acknowledged by the opposition division in its decision, by stating that “the film-forming properties are dependent on the reaction conditions and the polymers do not automatically form a film in any situation”.

As regards documents D12-D14, the following was observed:
- As noted by the opposition division on page 7 of the decision, D12 was published after the priority date of the patent and was not known at the date of filing. Therefore, D12 did not form part of the relevant state of the art and could not be considered.
- D13 only mentioned Gantrez S-96 and S-97. There was no mention in D13 of Gantrez S-95, MS-955 or S-97BF.
- D14 was solely concerned with Gantrez AN copolymers and nowhere in this document were any of the exemplary co-polymers used in the examples of the patent identified.

A key passage in the "A" publication was paragraph [0018]. The skilled reader was in no doubt that the co-
polymer – or “deposition aid” had to be soluble. However, although the co-polymer was soluble when it was dissolved, it could be re-dissolved following drying. This was in contrast to co-polymers which did not re-dissolve after drying, and were specifically taught by the application as filed to be disadvantageous. It was clear to the skilled reader that in the context of the claimed composition, the reference to a polymer being “not a film-forming polymer” was a reference to the polymer being capable of re-dissolving following drying. This in turn prevented build-up of the deposition aid on the teeth, which was a problem with compositions that did not have this re-dissolving property.

It was thus clear from the patent that the polymers used in the invention should not form films on teeth and not build up on teeth. Water solubility of the used polymers was required in order to avoid build-up of the deposition aid on teeth. The skilled person on reading the patent would have understood that Gantrez polymers, which were water soluble according to D13, would have met this criterion. Indeed, it was clearly possible to reproduce the invention on the basis of the original application documents, especially in view of the examples which all used Gantrez polymers according to the invention, without any inventive effort and undue burden.

As stated by the opposition division in its decision, this problem at best related to one of clarity (Article 84 EPC) rather than sufficiency of disclosure.

Admission of auxiliary requests 1 to 4 into the proceedings
Said requests were filed in response to the Board’s communication, whose negative opinion as regards sufficiency of disclosure was a surprise to the respondents.

Auxiliary request 4 - Article 123(3) EPC

Claim 1 was restricted to the 4 co-polymers which were shown to work. Said polymers fell under the definition “not a film-forming polymer”, and therefore this amendment could not extend the scope of protection.

XIV. Requests

The appellant requested that the decision under appeal be set aside and that the patent be revoked. Additionally, he requested that auxiliary requests 1 to 4 filed by the respondents with letter of 18 December 2018 not be admitted into the proceedings.

The respondents requested that the appeal be dismissed, alternatively, that the decision under appeal be set aside and the patent be maintained on the basis of one of auxiliary requests 1 to 4 filed with letter of 18 December 2018.

Reasons for the Decision

1. Main request - Sufficiency of disclosure

1.1 Claim 1 of the main request refers to an oral care composition comprising as essential elements a pigment and a water soluble deposition aid for said pigment.

Said deposition aid is characterized in that:
- it is a polymer having a molecular weight of 200,000 or greater,
- it is not a film-forming polymer,
- it is selected from co-polymers of maleic anhydride with methyl vinyl ether, in which the anhydride moiety may be in a partially or fully hydrolysed or alcoholysed form.

The description of the published patent application EP 1 935 395 A1 further defines the water soluble deposition aid in particular in paragraph [0018], as follows: "In the context of this invention, a "soluble" deposition aid is a material that is soluble in water, typically having a solubility of 0.5% or greater, and more typically 5% or greater by weight, at 25 deg. C. Further, such a material remains soluble following drying - i.e. it can be redissolved following drying. Such materials are typically polymers, but are not film-forming polymers. Water solubility is required in order to avoid build up of the deposition aid on the teeth, something that can also be a particular problem with film-forming polymers."

The description of the patent application quotes further in paragraph [0020] that "without wishing to be bound by theory, it is believed that the insoluble deposition aid works by having affinity for both the pigment and the surface of the teeth, the deposition aid serving as a link between the two."

The description of the patent application mentions in paragraphs [0026]-[0028] as typical co-polymers of maleic anhydride with methyl vinyl ether to be used in accordance with the invention the Gantrez® type polymers, namely:
Gantrez S-95: molecular weight 216,000; free acid;
Gantrez S-96: molecular weight 700,000; free acid;
Gantrez S-97: molecular weight 1,500,000; free acid;
and Gantrez MS-955: molecular weight 1,060,000;
calcium/sodium salt.

The preferred polymer is Gantrez S-97, which is also
used in all examples of the patent application.

The description does not mention any alternative co-
polymers of maleic anhydride with methyl vinyl ether
other than the Gantrez type polymers to be used for
performing the invention.

1.2 Several cited documents show and prove however that the
copolymers of maleic anhydride with methyl vinyl ether
disclosed in the description of the patent application,
namely the Gantrez type co-polymers which have been
disclosed in the description as falling under the
definition of the deposition aid of the invention, are
in fact effective film-forming agents.

1.2.1 D14 relates to Gantrez AN copolymers, which are
poly(methylvinylether/ maleic anhydride) copolymers
instead of the poly(methylvinylether/ maleic acid)
copolymers of the corresponding range Gantrez S (see
D14, page 3, first par.). According to D14, said
Gantrez AN forms the free maleic acid form when
dissolved in water or alcohols, thus the form
corresponding to the Gantrez S range; it is furthermore
known from D14 that aqueous or organic solutions of the
copolymer Gantrez AN form films (see D14, page 11). It
is therefore implicit from D14, that the free acid
forms of the copolymers Gantrez AN, which is the
copolymer corresponding to the range of product Gantrez
S copolymers, has film-forming properties. It is also
explicit from D14 that the Gantrez polymers are water-soluble, and for this reason would redissolve in water after drying.

1.2.2 D10 and D11 relate to the use of antibacterial-enhancing agents (AEA), which are generally anionic film-forming agents which are thought to attach to tooth surface and form a continuous film over the surfaces, thereby preventing bacterial attachment to the tooth surfaces (see D10, col 10, 1. 51-56; see D11, col 10, 1. 41-46). Preferred AEA polymers are co-polymers of maleic anhydride with methyl vinyl ether, such as in particular Gantrez AN and Gantrez S-97 (see D10, col. 9, 1. 4-13 and D11, col 8, 1. 63-col. 9, 1. 4). Example 1 of D10 and examples 1, 3,4 and 5 of D11 show aqueous compositions comprising Gantrez S-97 as antibacterial-enhancing agents, thus film-forming agents. It is therefore explicit from D10 and D11 that at least the preferred co-polymer of the present invention, namely Gantrez S-97, has film-forming properties, and more specifically is a teeth film-forming agent.

1.2.3 It is also explicit from D12 and D13 that the co-polymers of maleic anhydride with methyl vinyl ether have film-forming properties. D12 explicitly attributes film-forming properties to the co-polymer Gantrez MS-955 and to the Gantrez S range of products (see D12, page 62). The same film-forming properties are disclosed in D13 for the Gantrez S polymers, (see pages 4 and 5). Even though it appears that documents D12 and D13 have been published after the priority and filing dates of the contested patent, respectively in 2009 and 2013, their teaching confirms nevertheless what a skilled person indeed knew about said Gantrez polymers,
which is in any case confirmed by the teaching of the further documents D10, D11 and D14.

1.2.4 It appears therefore that the preferred co-polymers of maleic anhydride with methyl vinyl ether of the invention, namely Gantrez S-95, S-96, S-97 and MS-955 have effective film-forming properties, contrary to the definition of the claimed invention. The description does not mention any other alternative co-polymers of maleic anhydride with methyl vinyl ether, and does not identify which of said co-polymers of maleic anhydride with methyl vinyl ether would not be a film-forming polymer.

Consequently, the skilled person is not in a position to select a co-polymeric deposition aid which has the recited claimed chemical composition and has the recited physical property of not being a film former from the teaching of the contested patent.

Hence, the invention as defined in the independent claim 1 of the main request cannot be performed by a person skilled in the art without undue burden.

1.3 One of the respondent's main argument was that the key phrase "not a film-forming polymer" had to be understood that whether indeed a co-polymer was a "film-forming polymer" or not depended on the conditions in which the co-polymer was used, and that the ability of any such co-polymer to film-form was clearly a contextual property, in essence that said co-polymers do not form a film when used in oral care compositions, and particularly not on the teeth.

This argument could however not be followed by the Board for the following reasons.
1.3.1 The definition of the co-polymer as "not a film-forming polymer" is not further defined or restricted in claim 1 of the main request by any contextual property or behavior, and has to be understood as being an intrinsic property of the co-polymer. The claimed invention excludes thus explicitly any co-polymer having intrinsic film-forming properties, namely all Gantrez type polymers, which are the only disclosed embodiments.

1.3.2 The description does not specify this contextual property neither. The description provides a clear teaching that a build-up or an accumulation of the polymer should be avoided onto the teeth (cf. par. [0018] of EP 1 935 395 A1 and point 1.1 above), but does not further define or specify what is meant by the avoidance of build up of the deposition aid on the teeth and provides even inconsistent explanations. The description mentions indeed further that "it is believed that the insoluble deposition aid works by having affinity for both the pigment and the surface of the teeth, the deposition aid serving as a link between the two", indicating clearly that the co-polymer is deposited onto the teeth, i.e that it forms a film. (cf. publication EP 1 935 395 A1, par. [0020])

1.3.3 The existence of contextual properties linked with an application of the co-polymers on the teeth is in any case clearly and explicitly denied by the teaching of documents D10 and D11, since said documents disclose explicitly the film-forming properties of the polymers AN and S-97 over the teeth surfaces.

D14 also repeatedly mentions that in water, the Gantrez polymers form "flexible, clear films" or can be used as
"a protective colloid, film former" (see D14, page 3); this teaching is confirmed by D13 and D12, in particular in the context of oral care formulations (see D13 page 4 and D12, page 62).

1.4 Another argument of the respondents was that a skilled person would not have any difficulty in reproducing the invention in view of the examples of the patent and the commercial availability of the disclosed polymers.

This argument could also not be followed, since the assessment whether the patent discloses the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art, relates to the reproduction of the claimed invention and not to the reproduction of the examples. Moreover, the fact that all disclosed co-polymers were commercially available is irrelevant.

1.5 Consequently, the main request does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art and does not satisfy the requirements of Article 100(b) EPC.

2. Admission of auxiliary requests 1 to 3 into the proceedings

2.1 These requests have been filed after the issue of the Board's communication, thus at a late stage of the appeal proceedings, and constitute new requests which do not correspond to any request filed earlier in the appeal proceedings.

2.2 According to the respondents, the submission of these requests was a response to the Board's communication,
whose preliminary opinion surprisingly overruled the
decision of the opposition division as regards
sufficiency of disclosure.

2.3 In the Board's view, the objection of sufficiency of
disclosure was long known to the respondents, since it
was already present and discussed at length in the
opposition proceedings and pursued again by the
appellant in its grounds of appeal. As a matter of
fact, it was clear from the beginning of the opposition
and appeal proceedings that the assessment of
sufficiency of disclosure would be a major issue in the
present case.

Moreover, the Board's communication did not contain any
new arguments or facts that were not discussed in the
decision of the opposition division or presented by the
appellant in its statement of grounds of appeal.
A discussion of this ground can therefore not
constitute a surprise to the respondents. A change of
opinion as to the decision of the opposition division
can neither constitute a surprise, since the
appellant's appeal is aimed at reversing the opposition
division's decision, and accordingly the respondents
should be prepared for this situation.

Consequently, the Board's communication cannot be taken
as a justification for the submission of these new
requests at this late stage of the proceedings.

2.4 Given the current state of the proceedings, and the
fact that any amendment to a party's case after it has
filed its ground of appeal or reply may be admitted
and considered at the Board's discretion, the Board
exerts said discretionaty power and does not admit
these requests into the proceedings.
Consequently, auxiliary requests 1 to 3 are not admitted into the proceedings (Article 13(1) RPBA).

3. Admission of auxiliary request 4 into the proceedings

The subject-matter of claim 1 of auxiliary request 4 has been amended by the specification of the polymeric deposition aid, namely "selected from Gantrez S-95 (molecular weight 216,000 free acid), Gantrez S-96 (molecular weight 700,000, free acid), Gantrez S-97 (molecular weight 1,500,000, free acid) and Gantrez MS-955 (molecular weight 1,060,000, calcium/sodium salt)".

This request corresponds to auxiliary request 2 filed in response to the statement of grounds of appeal. It was therefore present in the appeal proceedings at the earliest stage of said proceedings. For this reason, this request is admitted into the proceedings (Article 12(1) RPBA).

4. Auxiliary request 4 - Article 123(3) EPC

The subject-matter of claim 1 of auxiliary request 4 has been restricted to the specific co-polymeric deposition aids of the invention, namely Gantrez S-95, Gantrez S-96, Gantrez S-97 and Gantrez MS-955. The specification that the deposition aid "is not a film-forming polymer" has furthermore been deleted in claim 1 of auxiliary request 4.

As discussed above (see point 1.2), said co-polymers Gantrez S-95, Gantrez S-96, Gantrez S-97 and Gantrez MS-955 are effective film-forming polymers.
Since claim 1 as granted mentioned that the co-polymeric deposition aid "is not a film-forming polymer", the subject-matter of claim 1 of auxiliary request 4 has now been extended to film-forming polymers and thus has been amended in such a way as to extend the protection it confers. The fact that the claimed co-polymers were presented as the preferred embodiments in the description does not have any incidence, since the assessment of the requirements of Article 123(3) EPC needs to be performed on the claimed subject-matter and not on the content of the description.

Consequently, auxiliary request 4 does not meet the requirements of Article 123(3) EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairman:

D. Hampe J. Riolo

Decision electronically authenticated