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Datasheet for the decision of 15 January 2013

Case Number: T 1637/09 - 3.3.02

Application Number: 96912744.8

Publication Number: 820265

IPC: A61K 6/10

Language of the proceedings: EN

Title of invention:
Improved polyvinylsiloxane impression material

Patentee:
DENTSPLY International Inc.

Opponent:
3M Innovative Properties Company

Headword:
Polymerizable polyorganosiloxane composition/DENTSPLY

Relevant legal provisions:
EPC Art. 83
RPBA Art. 13

Keyword:
"Main request, first and second auxiliary requests: Admissibility - (yes)"
"Third auxiliary request: Admissibility (no)"
"Sufficiency of disclosure (no)"

Decisions cited:
-

Catchword:
-

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Case Number: T 1637/09 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 15 January 2013

Appellant: (Opponent)
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Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted 5 June 2009 concerning maintenance of European patent No. 820265 in amended form.**

Composition of the Board:

Chairman: U. Oswald
Members: M. C. Ortega Plaza
R. Cramer

Summary of Facts and Submissions

I. European patent No. 0 820 265, based on European patent application No. 96912744.8, which was filed as an international application published as WO 96/32088, was granted with 24 claims.

Claim 1 as granted read as follows:

"1. A polymerizable polyorganosiloxane composition forming a dental impression having a tear strength of at least 1.38 MPa (200psi) and a contact angle with water of less than 50° at three minutes, said composition comprising:

(a) a QM resin containing vinyl groups;
(b) a linear vinyl terminated polydimethyl-siloxane fluid forming with said QM resin a dispersion having a vinyl content of 0.16 to 0.24 mmole/g;
(c) an organohydrogen polysiloxane for cross-linking said vinyl groups;
(d) an organoplatinum catalyst complex for accelerating polymerization of said components;
(e) a retarder component in sufficient amount for temporarily delaying the onset of said polymerization;
(f) a filler; and
(g) a surfactant that imparts wettability in said composition".

Independent claim 18 as granted reads as follows:

"18. Use of a composition according to any one of claims 1 to 15 for making a dental impression".

II. Opposition was filed, and revocation of the patent in its entirety was requested pursuant to Article 100(c), 100(b) (lack of sufficiency of disclosure) and 100(a) EPC (lack of inventive step and non-patentability within the meaning of Article 52(4) EPC 1973).

III. The following documents *inter alia* were cited in the opposition and appeal proceedings:

D1 EP-A-0522341
D3 WO 93/17654
D4 US-A-4657959
D11 E. Lindner, J. Hoinkis "Chemie für Ingenieure", 11th edition, 1997, pages 70-71
D12 Holleman-Wiberg, Lehrbuch der Anorganischen Chemie, 91.-100. Auflage, N. Wiberg, 1985, pages 764-765

IV. The present appeal lies from an interlocutory decision of the opposition division maintaining the patent in amended form on the basis of the main request filed during the oral proceedings before the opposition division (Articles 101(3)(a) and 106(2) EPC).

Claim 1 of the main request before the opposition division was identical to claim 1 as granted.

V. The opposition division considered that the ground of opposition under Article 100(c) EPC did not prejudice the maintenance of a patent since granted claims 19 and 20 had been deleted.

The opposition division further considered that the ground of opposition under Article 100(a) pursuant to Article 52(4) EPC 1973 (Article 53(c) EPC 2000) did not

prejudice the maintenance of a patent since the subject-matter of claim 22 (identical to claim 24 as granted) did not concern a diagnostic method practised on the human/animal body. The opposition division referred to Enlarged Board of Appeal opinion G 1/04 OJ EPO 2006, 334 and stated that the subject-matter claimed in claim 22 did not relate to a diagnostic method *stricto sensu*.

As regards the ground of opposition under Article 100(b) EPC, the opposition division considered that the disclosure did not contain any "*deficiencies*" "*which would hinder*" the skilled person in carrying out the invention and that the onus was on the opponent "*to show the lack of dispersion in the imprint preparation*".

As regards inventive step, the opposition division considered document D4 as closest prior art since D1 addressed "*a different objective problem, namely the quick polymerization of a QM resin, without admixture of a retarder or a tenside for wettability reasons, in order to achieve a hard resin for bite registration*". The opposition division was of the opinion that the teaching in document D3 that a certain dental impression material may also be used as bite registration material had to be disregarded as not being of general applicability. The opposition division defined the problem to be solved as "*the provision of controlled QM resin cross-linking polymerization using a retarder, and reaching an improved wettability, suitable for obtaining accurate and detailed dental impressions*".

In the opposition division's view, the nearest prior art D4 had been taken into consideration by the "*applicant*" in Figure 1, showing an improvement in wetting contact angle curve A (composition of the invention), compared with curve B and curve C of the nearest prior art D4. Additionally, the opposition division considered that "*the patentee had agreed*" to indicate in the amended description that the examples for which there was a "*discrepancy*" in relation to "*certain characteristic features*" appearing in claim 1 and in paragraph [0017] were reference examples.

VI. The opponent (appellant) filed an appeal against said decision and filed grounds of appeal. It requested that the decision under appeal be set aside and the patent be revoked. Moreover, the appellant filed with its grounds of appeal further documents (D11 and D12) and some "comparative examples" (containing colour photographs) in order to show that no scattering for a red laser beam was observed in two commercially available "VQM resins in divinylpoly(dimethyl siloxane)s", demonstrating that they were solutions.

VII. The respondent (patent proprietor) filed a response to the grounds of appeal in which it requested that the appeal be dismissed and gave reasons. It also requested a copy of the "comparative examples" and a readable copy of document D11.

VIII. The board sent a colour copy of the "comparative examples" to the respondent.

IX. The appellant with a letter dated 10 May 2010 filed counter-arguments to the respondent's reply and a readable copy of document D11.

X. Summons to oral proceedings pursuant to Rule 115(1) EPC were sent to the parties on 7 September 2012. The board sent a communication pursuant to Article 15(1) RPBA as an annex thereto.

In said communication the board pointed out that the main request contained several independent claims which had to be assessed separately. Moreover, the board expressed the preliminary opinion that, as the facts on file stood, the method in claim 22 did not concern a diagnostic method since neither the teeth nor the gingival tissues were diagnosed, and that no direct link could be seen between the claimed method of making a dental impression and a diagnosis of a pathophysiological condition of clinical relevance. Additionally, the board expressed the opinion that claim 18 did not concern a diagnostic method either.

As regards Article 100(c) EPC the board pointed out that the basis for claim 21 in the application as filed was not self-evident and gave reasons.

The board also expressed in said communication a preliminary opinion about the issues under dispute pursuant to Article 100(b) EPC. The board sent to the parties a copy of page 1014 of the Römpp Chemie Lexikon 10th edition 1997, Georg Thieme Verlag (G1).

The board also made some comments in relation to the problem-solution approach and reminded the parties that

the admissibility of any requests and submissions filed after the communication of the board would be considered at the oral proceedings, in particular under Article 13 RPBA.

XI. The appellant filed a reply to the board's communication with a letter dated 5 December 2012. It stated that there was no basis in the application as filed for claim 21 and gave reasons. The appellant filed arguments in relation to the grounds pursuant to Article 100(b) EPC, the term "dispersion", document G1 and the claimed subject-matter. It also filed further arguments in relation to the grounds under Article 100(a) EPC pursuant to inventive step and the product claims.

XII. The respondent filed a reply to the board's communication with a letter dated 17 December 2012. It filed therewith a new main request and two auxiliary requests (first and second). None of the new filed requests contained claims 21 and 22 of the main request previously on file. The respondent stated that the new requests no longer gave rise to concerns in relation to Article 100(c) EPC. It also submitted counter-arguments in relation to sufficiency of disclosure (Article 83 EPC).

Claim 1 of the new main request was identical to claim 1 as granted. Claim 18 of the new main request was identical to claim 18 as granted.

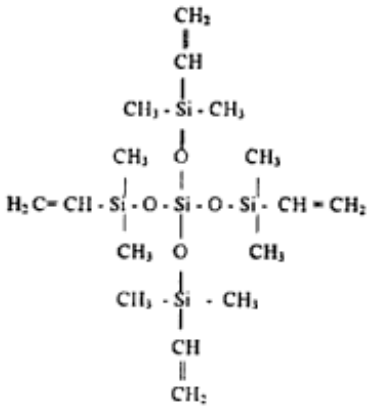
Claim 1 of the first auxiliary request differs from claim 1 of the main request in that the following is

added after the expression "said composition" at the end of the previous claim 1:

", wherein said QM resin comprises a polyorganosiloxane comprising units of $SiO_{4/2}$ and up to four units of $R^1R^2{}_2SiO_{1/2}$ wherein
R^1 is unsaturated hydrocarbon and
R^2 is alkyl or aryl".

Claim 1 of the second auxiliary request differs from claim 1 of the first auxiliary request in that after the term "aryl" the following has been added:

", and wherein said QM resin comprises the formula



XIII. Oral proceedings took place on 15 January 2013.

XIV. At the oral proceedings before the board the respondent filed a third auxiliary request.

Claim 1 of the third auxiliary request read as follows:

"1. **Use of** a polymerizable polyorganosiloxane composition forming a dental impression having a tear

strength of at least 1.38 MPa (200psi) and a contact angle with water of less than 50° at three minutes, said composition comprising:

(a) a QM resin containing vinyl groups;
(b) a linear vinyl terminated polydimethyl-siloxane fluid forming with said QM resin a dispersion having a vinyl content of 0.16 to 0.24 mmole/g;
(c) an organohydrogen polysiloxane for cross-linking said vinyl groups;
(d) an organoplatinum catalyst complex for accelerating polymerization of said components;
(e) a retarder component in sufficient amount for temporarily delaying the onset of said polymerization;
(f) a filler; and
(g) a surfactant that imparts wettability in said composition, **wherein said surfactant comprises an HLB of 8-11 and a pH of 6-8, for making a dental impression**". (*emphasis added*)

XV. The appellant's arguments, as far as relevant for the present decision, may be summarised as follows:

The appellant objected to the admissibility of the respondent's requests filed with the letter of 17 December 2012 since they were late-filed and did not relate to a reaction to any new issues recently raised. In the appellant's view these requests could have been filed during the opposition proceedings.

The appellant also objected to the admissibility of the third auxiliary request filed at the oral proceedings before the board, since it could have been filed earlier. Moreover, this request was not *prima facie*

allowable and opened for the first time new issues such as how to address the measurement of the pH in relation to the surfactant present in the composition, and the specification of a certain HLB range of values for the surfactant and its impact in the compositions for which a use was now claimed. These new features concerning the surfactant were introduced for the first time in the use claim, since they were not present either in the claims as granted or in the claims maintained by the opposition division.

The appellant did not have any objections within the meaning of Article 123 EPC against the main request or the first and second auxiliary requests.

As regards the ground of opposition pursuant to Article 100(b) EPC the appellant submitted the following:

Claim 1 of the main request requires that the QM resin containing vinyl groups and the linear vinyl terminated polydimethyl-siloxane fluid have to form a dispersion. There is no information in the description how such a dispersion should be formed. The description did not even contain any mention of the required proportions in general terms. Therefore, in the absence of any indication in the description of the patent in suit, the knowledge of the skilled person had to be invoked. The appellant further submitted that it had filed several documents and further evidence in response to the opposition's division observations. Document D11 reflected the general understanding of the skilled person. Document D11 taught that for constituting a dispersion at least a biphasic material with a

continuous phase and some material dispersed therein were needed which gave rise to light scattering (Tyndall effect). If there was no Tyndall effect, then there was no dispersion. Document D12 (a book also showing the general knowledge of the skilled person) taught that a dispersion which did not give rise to Tyndall effect was a real solution, a "molecular dispersion". Thus, there was an important difference in calling something a "dispersion" or a "solution". In patent terms a solution would not be considered as novelty-destroying for a dispersion. There was a lack of information in the patent in suit in relation to the dispersions, and the skilled person would have taken the Tyndall effect to establish whether something was a dispersion or a solution. Moreover, the patent in suit did not teach the skilled person how to obtain a dispersion with a vinyl content of 0.16 to 0.24 mmole/g from a QM resin containing vinyl groups together with a linear vinyl terminated polydimethyl-siloxane fluid. QM resins fulfilling the definitions given in the patent in suit dissolved in the vinyl terminated polydimethylsiloxanes and thus did not form dispersions. The appellant referred to the experimental data submitted with its grounds of appeal which showed that the composition consisting of commercially available QM resins containing vinyl groups in vinyl terminated polydimethyl-siloxane fluid and having a viscosity within the viscosity range disclosed in the patent in suit were real solutions and not dispersions since they did not show the Tyndall effect. Moreover, the experimental data also showed that even if a composition of higher viscosity constituted of QM resin containing vinyl groups in vinyl terminated polydimethyl-siloxane fluid was taken, it was still a

real solution without Tyndall effect. Therefore, the appellant submitted that it had not been able to obtain the dispersions defined in claim 1. The mere information in paragraph [0025] of the patent in suit that a company in Pennsylvania sold such dispersions did not identify either the products or the actual materials and was insufficient for the skilled person trying to reproduce the claimed invention.
Additionally, the appellant argued that the skilled person was told in paragraph [0025] of the patent in suit that the QM resin provided a vinyl concentration in the dispersion with the vinyl-terminated polydivinylsiloxanes of at least about 0.16 mmole/g, that the vinyl concentration was preferably 0.16-0.24 mmole/g, and that the amount of QM resin was preferably about 20-25% by weight of the dispersion. The appellant referred in this respect to its submissions in point 3.2 of the grounds of appeal. In particular, the most preferred QM resin containing vinyl groups was depicted at the top of page 5 of the patent in suit. It was a QM resin with a molecular weight of 432.89 g/mole. Thus, 1 g of this compound corresponded to 2.31 mmole. Since this compound contained four vinyl groups, the vinyl concentration was four times 2.31 mmole/g, i.e. 9.24 mmole/g. Considering that the preferred amount in the dispersion of QM resin was 20-25% by weight as stated in paragraph [0025] of the patent in suit, even making a "dispersion" using said QM resin in pure unfunctionalised polydimethylsiloxane would result in a vinyl concentration of 1.85 mmoles/g (0.2 times 9.24 mmoles/g). Thus, the resulting vinyl concentration would be 10 times higher than it should be according to claim 1. Using instead of pure unfunctionalised polydimethylsiloxane a vinyl terminated

polydimethylsiloxane would not decrease the vinyl content of the QM resin in the preferred concentration. Therefore, the skilled person would not be able to work out the claimed subject-matter. The examples in the patent in suit did not help the skilled person either, since they merely referred to QM resin dispersions without any information as to how they were prepared. The reference in brackets to certain viscosity ranges, without the measuring conditions, was clearly insufficient for establishing how to provide said dispersions.

The appellant further submitted that it had had a willingness to understand the claim and that the allegation that in the field of polymer chemistry a solution should be called a dispersion was strongly to be rejected. Document D1 disclosed on page 5, line 47, that the QM resins were **dissolved** in the vinyl terminated polydimethylsiloxanes. Moreover, a dispersion did not necessarily include a molecular dispersion for which one would use the term solution. The mere requirement of having two phases was not enough. Polymer chemistry did differentiate between dispersions and solutions. The polymer chemist made a clear difference between the expressions "emulsion polymerisation" (polymerisation liquid in liquid non-miscible) and "solution polymerisation". The patent proprietor had chosen the term "dispersion" in the patent in suit and was responsible for the content of its patent. The skilled person working with solutions would have thought that it was working outside the claim. If the respondent meant now that solutions were also included, this was in clear contrast to the description. The last sentence on page 4 of the patent

in suit "a most preferred composition is represented by the formula …" left no room for interpretation. Even considering the respondent's allegation that one obtained a mixture with a different content of QM resin, one would need ten times the molecular weight to obtain an adequate vinyl content. Then the QM resin containing vinyl groups most preferred would be present in an amount of 1%. The skilled person in the light of the description would not have considered the most preferred compound to be in an amount of 1%.

The appellant objected to the respondent's explanations in relation to the vinyl content of the dispersions containing the compound on top of page 5 of the patent in suit. The QM resin containing vinyl groups at the top of page 5 was in accordance with feature (a) in claim 1, and it had to be dispersed in a vinyl terminated polydimethylsiloxane fluid. Even if a polydimethyl siloxane fluid without vinyl content was taken, it was not possible to achieve a vinyl content within the claimed values for the most preferred concentrations. If the skilled person prepared the QM resin at the top of page 5 of the patent in suit he would take compositions in which it was present in a significant amount, i.e. in amounts of at least 70%. Therefore, when 20 to 25% of said composition was taken one would still not get the vinyl content in claim 1.

The question to be answered was not whether the skilled person could prepare a QM resin containing vinyl groups by modifying the M units in order to arrive at a QM resin with a vinyl content within the range defined in claim 1, but whether or not the patent in suit sufficiently disclosed the claimed invention. The

appellant further submitted that it had shown that even following the most preferred teaching of the disclosed invention one would not fall within the claim. No single example illustrated how to prepare the dispersions in feature (b) of claim 1 or how to adjust their vinyl content. The dispersions mentioned in paragraph [0025] of the patent in suit as commercially available were insufficiently identified.

There was a lack of teaching in the patent in suit in relation to what kind of QM resin containing vinyl groups was to be prepared for the dispersions mentioned in the examples. Moreover the composition illustrated in example 13 which apparently used QM resin dispersions such as those in other examples did not achieve an appropriate tear strength. The skilled person trying to reproduce the claimed invention would need a research program.

As regards the first and second auxiliary requests, the appellant maintained *mutatis mutandis* the arguments against the main request since the introduced modifications did not overcome any of the objections against the subject-matter in claim 1 of the main request.

The composition of example 13 differed in several respects from the compositions in examples 1 to 3. Therefore, it was not self-evident why the tear strength was achieved by the composition in examples 1 to 3 and not by the composition in example 13. If the amount of catalyst was so essential for achieving the effect, it was further questionable why it was not defined in claim 1.

XVI. The respondent's arguments, as far as relevant for the present decision, may be summarised as follows:

The requests filed with the letter of 17 December 2012 should be admitted into the proceedings. These requests had been filed in response to the board's communication sent as an annex to the summons. The amendments in the main request merely concerned the deletion of claims in order to simplify the discussions. The appellant could not have been taken by surprise. This also applied *mutatis mutandis* to the first and second auxiliary requests. The only difference was that granted claims 1 and 2 (first auxiliary request) and granted claims 1, 2 and 3 (second auxiliary request) had been combined. These amendments merely related to a limitation of the subject-matter in relation to the QM resin containing vinyl groups which was in accordance with the granted claims. Therefore, the undertaken amendments did not open new issues for discussion.
In relation to the admissibility of the third auxiliary request, the respondent stated that the arguments submitted for the other requests applied by analogy. Moreover, claim 1 derived from granted claim 18, which was an independent claim to be treated separately, as indicated in the board's communication sent as an annex to the summons.

The respondent further submitted that claim 1 had to be read with a willingness to understand. In polymer chemistry the term "dispersion" was to be understood broadly as molecules dispersed in a medium. Since molecules were very large one could have a single molecule forming one phase, but it was still called a

dispersion (which also included a molecular dispersion). Even if they did not show a Tyndall effect they were still dispersions since they had two siloxane resin components as expressed in feature (b) of claim 1, and could be prepared according to standard procedures. The QM resin containing vinyl groups might in fact be constituted by different molecules obtained by hydrolysis of polysiloxanes. This mixture was component (a) in claim 1. The dispersion contained molecules, each having a certain number of final groups. A molecule as depicted at the top of page 5 of the patent in suit was a preferred structure but the dispersion did not consist only of this compound as QM resin. The vinyl terminated polydimethyl siloxane was used for lowering the vinyl group content within the teaching of the disclosure. The respondent cited paragraph [0025] of the patent in suit and stated that one had to adjust the vinyl content for the QM resin and then add the linear vinyl terminated polydimetyl siloxane. Claim 3 as granted stated that the "QM resin comprises the formula …".

Asked by the board in which passage of the description it was stated that the QM resin containing vinyl groups was a mixture, the respondent replied that QM resins were always mixtures obtained by hydrolysis of polysiloxanes bearing at their end part one hydrolysable group. One QM structure was preferred but one found it together with higher "aggregates" owing to the statistical nature of the hydrolysis process. In this context the respondent cited paragraph [0012] of the patent in suit, and more particularly line 30 where the wording "comprises" had been used. The respondent also referred to document D1, page 5, lines 43-52, and

stated that it did not specify any formula for the QM resin and that it was a common practice to adjust the vinyl content with regard to the siloxane. Therefore, it was contrary to the general knowledge in the field to use a single component since mixtures were used which were characterised by parameters. The QM resin containing vinyl groups at the top of page 5 of the patent in suit was one component in the mixture.

The respondent further stressed that paragraph [0025] of the patent in suit referred to commercially available dispersions which were suitable for the invention. Although the appellant had denied that one could not modify the composition by lowering the vinyl content, it was possible to take one gram of dispersion with a high vinyl content and add thereto sufficient amount of an adequate linear vinyl terminated polydimethylsiloxane (e.g. choosing a polymer with sufficient length) to lower the total vinyl content. The compound depicted at the top on page 5 is the QM resin with highest vinyl content, when referring to it one always spoke of mixtures with other species having a lower vinyl content. Thus, when speaking of 20 to 25% not only the compound at the top of page 5 was concerned but other species also. Paragraph [0024] of the patent in suit defined QM resins of different vinyl contents, thus it was simple for the skilled person to arrive at the vinyl content defined in claim 1.

The respondent further stated that to make the dispersions was prior art knowledge and that it had not invented the QM resins, which were known products. Thus, in its opinion, in order to meet the criteria of sufficiency of disclosure it was only necessary to

disclose technical features such as the vinyl content and the technical effects achieved in terms of a tear strength and a contact angle with water. The mechanical properties of the compositions were determined by the cross-linking. Therefore, the important feature in relation to the polysiloxane (c) were the vinyl groups of the dispersion defined in (b).

Example 13 showed that the amount of platinum catalyst mattered (example with least amount of catalyst). Examples 1 to 3 gave wonderful results. However, if the cross-linking was prevented for some reason then one would not get the targeted effect. The catalyst was not the only reason for influencing the tear strength; also the filler content influenced the tear strength. This could be understood by looking at the examples. The invention concerned the teaching that with a certain vinyl content you could influence the tear strength to have the adequate values.

The first auxiliary request made it clear that some other structures were possible and the second auxiliary request employed the wording "comprises" in relation to the particular QM resin.

XVII. The appellant (opponent) requested that the decision under appeal be set aside and that patent No. 0820265 be revoked.

The respondent (patent proprietor) requested that the decision under appeal be set aside and the patent be maintained in amended form on the basis of the main request filed with the letter of 17 December 2012, or alternatively, on the basis of the first or second

auxiliary requests also filed with the letter of 17 December 2012.

Reasons for the Decision

1. *Admissibility*

1.1 The appeal is admissible.

1.2 *Admissibility of the claim requests*

1.2.1 Article 13(1) RPBA provides that any amendment to a party's case after it has filed its grounds of appeal or reply may be admitted and considered at the board's discretion. The discretion shall be exercised in view of *inter alia* the complexity of the new subject-matter submitted, the current state of the proceedings and the need for procedural economy. Article 13(3) RPBA provides that amendments sought to be made after oral proceedings have been arranged shall not be admitted if they raise issues which the Board or the other party or parties cannot reasonably be expected to deal with without adjournment of the oral proceedings.

1.2.2 The main request and the first and second auxiliary requests were filed with the letter dated 17 December 2012 as a direct reply to the comments in the board's communication sent as an annex to the summons to oral proceedings. The new main request differs from the main request serving as basis for the interlocutory decision of the opposition division in that the method claims 19 and 20, as well as the method claims 23 and 24, had been deleted. The deletion of the mentioned claims in

the main request is also undertaken in the first and second auxiliary requests.

The deletion of the claims mentioned above simplifies the discussions since, as a consequence, Article 100(c) EPC and Article 52(4) EPC 1973 are no longer under dispute for the amended sets of claims filed with the letter of 17 December 2012.
Moreover, the first and second auxiliary requests differ from the main request in that the definition of the QM resin containing vinyl groups is delimited by incorporation into claim 1 of dependent claim 2, or dependent claims 2 and 3 as granted. These amendments do not open new issues and are easily to handle.

Additionally, there was no objective reason justifying the filing of these amendments during the opposition proceedings, because the opposition division allowed the respondent's previous main request which contained the now deleted claims, and in which claim 1 was broader than claim 1 of the first and second auxiliary requests filed with the letter of 17 December 2012.

Therefore the main request and the first and second auxiliary requests filed with the letter of 17 December 2012 are admitted into the proceedings.

1.2.3 As regards the third auxiliary request, it was filed at the oral proceedings before the board. To justify its filing the respondent referred to the board's communication sent as an annex to the summons. However, said board communication merely identified use claim 18 of the main request serving as basis for the opposition division's decision as an independent claim.

Additionally, claim 1 of the third auxiliary request is not identical to claim 18 of the main request serving as basis for the opposition division's decision, but incorporates for the first time some features concerning the definition of the surfactant present in the composition. Thus, the respondent's allegation does not suffice as a valid justification for such a late-filing. In addition, the introduced amendments open new and complex issues for discussion at such a late stage of the proceedings. Therefore the third auxiliary request is not admitted into the proceedings.

2. *Article 100(c) EPC*

2.1 None of the amended sets of claims, main request and the first and second auxiliary requests, has been objected to under grounds pursuant to Article 100(c) EPC and the board sees no reason to differ.

3. *Article 100(b) EPC, sufficiency of disclosure (Article 83 EPC)*

3.1 The European patent shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

As reflected by the constant jurisprudence of the boards of appeal of the EPO, when determining whether there is sufficiency of disclosure the content of the patent, including the description and the examples, has to be investigated by the skilled person in the light of his general common knowledge in the technical field involved. Moreover, it is the claimed "invention" which has to be investigated. The general legal principle is

that the claims define the matter for which protection is sought and the examples illustrate specific ways of performing the invention.

As for the amount of technical detail needed for a sufficient disclosure, this is a matter which depends on an assessment of the facts of each particular case, such as the character of the technical field, and the actual technical detail disclosed.

3.1.1 Claim 1 of the main request is identical to claim 1 as granted. Claim 1 relates to a **polymerizable** polyorganosiloxane composition which is capable of forming a dental impression. The **polymerized** product forming a dental impression is characterised by the following parameters: a tear strength of at least 1.38 MPa (200psi) and a contact angle with water of less than 50° at three minutes. The polymerizable composition claimed in claim 1 has to able to lead, **after polymerization**, to a product fulfilling the functions determined by the parameters defined in the claim (see paragraph [0017] of the patent in suit).

The claimed product is the **polymerizable** composition which is characterised by its components (a) to (g) in claim 1.

Component (a) is broadly defined as a QM resin containing vinyl groups, and component (b) is broadly defined as a linear vinyl terminated polydimethyl-siloxane fluid. Furthermore, there is a condition to be fulfilled by components (a) and (b), namely that said linear vinyl terminated polydimethyl-siloxane fluid

forms with said QM resin a dispersion having a vinyl content of 0.16 to 0.24 mmole/g.

3.1.2 Although the patent in suit states in paragraph [0021] in relation to the "fluid" for forming the dispersion that "A **wide variety of organopolysiloxanes having at least two vinyl groups per molecule** are known for inclusion in the dental polysiloxane compositions of the invention **to form the dispersion** including a quadri-functional vinyl polysiloxane" (emphasis added), there is no particular prior art document being cited or referred to in relation to the formation of such dispersions. Thus, this passage in paragraph [0021] can only be taken as an acknowledgment that there is a wide variety of organopolysiloxanes having at least two vinyl groups per molecule, known to the skilled person, among which he has to choose the "fluid" for forming the dispersion.

Further in relation to the "fluid" for forming the dispersion, paragraph [0021] of the patent in suit states the following: "Each of these materials may be included in greater or lesser degree in accordance with the practice of the instant invention. Preferred for use herein are linear vinyl terminated polydivinylsiloxanes preferably a divinyl polydimethylsiloxane. Such polymers are sold **having varying average molecular weights with concomitant variations in viscosity**. It is preferred that these materials be selected to have a viscosity appropriate for the conditions to be experienced by the resulting silicone material" (emphasis added).

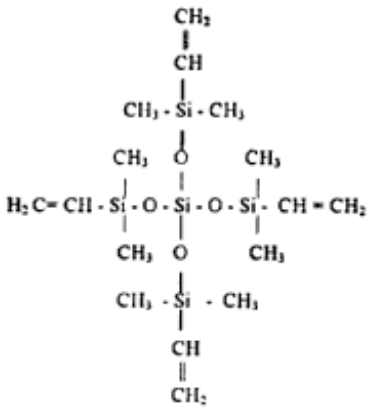
In relation to the dispersions and the dispersing "fluid", paragraph [0022] states: "The dispersions of interest have a viscosity range of 5,000-60,000 cps. In practice, it is convenient to employ a blend of the **dispersing polymers having different viscosities and physical properties** to provide compositions having a desired thixotropicity and viscosity" (emphasis added).

Furthermore, in paragraph [0023] the patent in suit states in relation to the viscosity of the dispersions and the organopolysiloxane "dispersing polymers" (which have to serve as "fluid" for the dispersions): "The dispersions of interest are preferably formed in two viscosity ranges: (1) a first dispersion having a viscosity of about 5,000-7,000 cps; and (2) second dispersion having a viscosity of about 45,000-65,0000 cps. While it is convenient to provide polysiloxane oligomers for this purpose having methyl substituents, other substituents may also be included in the compositions in accordance with this invention. Thus, alkyl, aryl, halogen, and other substituents may be included in greater or lesser degree as part of the vinyl polysiloxanes which are useful". Without any detailed disclosure, or specific mention of any particular prior art, paragraph [0023] ends up with the following lapidary statement: "Those of ordinary skill in the art will be able to determine which polysiloxanes are preferred for any particular utility from the foregoing considerations".

Thus, the only indications for the skilled person in relation to the dispersions are that their viscosity may vary within a broad range, namely 5,000 to 60,000

cps, and that the dispersing vinyl polysiloxane polymer is to be chosen accordingly.

As regards the quadri-functional polysiloxane QM resin containing vinyl groups to be dispersed in the vinyl polysiloxane fluid, the patent in suit states in paragraph [0024]: "The quadri-functional polysiloxanes, designated and known in the art as QM resins, provide improved tear strength to the polymerized impression composition, by increasing its resulting polymerized crosslink density". The patent in suit does not cite, however, any specific piece of prior art disclosing QM resins particularly suitable for the claimed invention. Paragraph [0024] further continues in a very general manner: "As is known, the QM resin is made up of: Q units of quadri-functional $SiO_{4/2}$; and M units, such as $R^1R^2{}_2SiO_{1/2}$ wherein R^1 is unsaturated, preferably vinyl and R^2 is alkyl, aryl or the like, such as methyl, ethyl or phenyl. In a preferred composition R^1 is vinyl and both R^2 are methyl".
Immediately thereafter paragraph [0024] states the following:
"A **most preferred** composition is represented by the formula (emphasis added):



".

No prior art document is cited in the patent in suit in relation to the preparation of this specific QM resin containing vinyl groups, nor is there any indication in the patent in suit that when mentioning said quadri-functional QM resin as the most preferred QM resin containing vinyl groups only a mixture is meant which contains the specific compound represented by the formula depicted above in certain amounts.

Moreover, even assuming for the sake of argument that the particular QM resin whose formula is depicted above is obtainable in admixture with other components and the skilled person would never use it as a 100% pure compound, there is no objective reason for only using fractions in which this most preferred quadri-functional QM resin would be in a low proportion within the QM resin (a) according to claim 1. Moreover, the patent does not contain any disclosure going in this direction.

Additionally, paragraph [0025] of the patent in suit states that: "The QM resin provides a vinyl concentration in the dispersions with the vinyl-terminated polydivinylsiloxanes of at least about 0.16 m-mole/g. Preferably, the **vinyl concentration is 0.16-0.24 m-mole/g**. The **amount of QM resin** is preferably about **20-25% by weight of the dispersion**" (emphasis added). This proportion of 20-25% by weight also relates to the proportion (expressed by weight) of the most preferred QM resin containing vinyl groups represented by the formula depicted above in relation to the polydivinylsiloxane fluid in which it is dispersed.

The calculations provided by the appellant in relation to the vinyl concentration provided by the most preferred QM resin at the top of page 5 of the patent in suit have not been disputed by the respondent. What has been disputed is what information the patent in suit actually provides to the skilled person trying to reproduce the invention.

The board considers that said calculations prove that when taking the most preferred QM resin containing vinyl groups within the ranges stated as most preferred of 20-25% by weight of the dispersion it is not possible to get the vinyl concentration of 0.16-0.24 m-mole/g, as defined in claim 1 of the main request. Therefore, the skilled person would be at a loss when trying to reproduce the claimed invention following the disclosure in the patent in suit.

The mere information in paragraph [0025] that "Such dispersions are sold by Miles, Inc. of Pittsburgh, Pennsylvania" does not help to fill the gap of an insufficient and contradictory disclosure. First of all, the alleged commercially available dispersions are not clearly identified, e.g. by means of a trade mark name and/or any other provider name or reference number. Furthermore, they are not identified either in relation to their constitution, in particular in relation to the nature and contents of the QM resin, or in relation to the vinyl concentration of the dispersion (in mmole/g).

The examples in the patent in suit do not further help the skilled person trying to reproduce the invention, since they merely mention "QM resin dispersions" showing different viscosities within two different viscosity ranges, namely 5,000-7,000 cps and 45,000-60,000 cps, respectively. The vinyl concentration of

the dispersions is not stated in the examples. Moreover, the examples do not contain any information as how to prepare the dispersions. They do not even state which are the QM resins and the vinyl terminated polydimethylsiloxane fluid which form the QM resin dispersions employed.

Additionally, the appellant has provided experimental data showing that the skilled person following his common general knowledge would rather obtain solutions (without Tyndall effect) and cited documents D11 and D12.

By contrast, the respondent has not provided any details as how to prepare successfully the dispersions constituting the products it claims. The burden of proving the facts that it alleges lies with the party invoking those facts. The respondent has merely referred to the examples, but the examples are devoid of any useful information in this respect. It has to be recalled that during opposition proceedings even some of the examples intended to illustrate the claimed invention were renamed as "reference" examples after it had been shown that there were serious discrepancies between the claimed invention and the "illustrative" examples. Therefore, the respondent whose arguments rest on the assertion that the skilled person would know how to prepare the dispersions mentioned in claim 1, without citing any particular piece of prior art and without giving any experimental details for at least one specific example of the dispersions, has not been able to discharge its onus of proof.

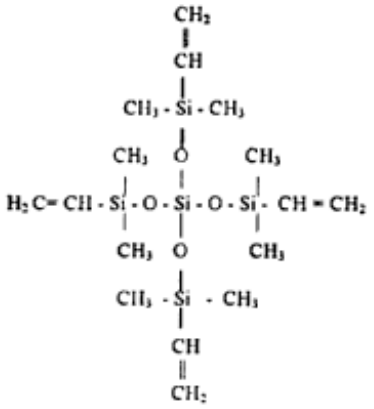
As regards the argument that although document D1 does not include any structural formula for the QM resin contained in the compositions its disclosure is enabling, it has to be said that document D1 not only states that the QM resins and their preparation are known, it also specifically cites three prior art documents (page 5, lines 43-44). Furthermore, document D1 refers to optical clear solutions and does not mention dispersions (page 5, lines 46-47).

3.1.3 In view of the above reasons, the main request fails for lack of sufficiency of disclosure pursuant to grounds under Article 100(b) EPC.

3.2 The reasons given above for the main request also apply *mutatis mutandis* to the first auxiliary request, since the mere specification in claim 1 of the QM resin containing vinyl groups as "said QM resin comprises a polyorganosiloxane comprising units of $SiO_{4/2}$ and up to four units of $R^1R^2{}_2SiO_{1/2}$ wherein
R^1 is unsaturated hydrocarbon and
R^2 is alkyl or aryl" does not overcome any of the major problems stated above in relation to the lack of information for successfully forming dispersions according to the claimed invention.

3.3 The reasons given above for the main request also apply by analogy to claim 1 of the second auxiliary request, which includes, in addition to the amendment in claim 1 of the first auxiliary request, the further specification:

"and wherein said QM resin comprises the formula



".

The fact that the most preferred QM resin containing vinyl groups is depicted in claim 1 does not change anything about the reasons given for the main request, which support the conclusion that there is insufficiency of disclosure also for the second auxiliary request. The fact that the term "comprises" is used in claim 1 of the second auxiliary request does not necessarily set a limitation as to the maximum content of the quadri-functional QM resin as component (a) in the composition claimed. Moreover, even considering that the quadri-functional resin represented by the formula depicted above would have to be in low amounts in order to attain the vinyl content defined in the claim, there is still a lack of sufficiency of disclosure since the description (including the examples) does not disclose the invention in a manner sufficiently clear and complete to allow the skilled person to reproduce the invention within the scope claimed without making use of his inventive skills.

3.4 Therefore the first and second auxiliary requests also fail for lack of sufficiency of disclosure pursuant to grounds under Article 100(b) EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent No. 0 820 265 is revoked.

The Registrar: The Chairman:

N. Maslin U. Oswald