

Internal distribution code:

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

**Datasheet for the decision
of 14 April 2015**

Case Number: T 1775/11 - 3.3.05

Application Number: 02781424.3

Publication Number: 1456125

IPC: C01B33/193, A61K6/00

Language of the proceedings: EN

Title of invention:

AMORPHOUS SILICA

Patent Proprietor:

PQ Silicas UK Limited

Opponents:

Evonik Degussa GmbH
Grace GmbH & Co. KG
J.M. Huber Corporation

Headword:

Amorphous silicas/PQ SILICAS UK LTD

Relevant legal provisions:

EPC Art. 83

Keyword:

Sufficiency of disclosure - undue burden (yes)

Decisions cited:

T 0032/85, T 0435/91, T 0809/07

Catchword:



**Beschwerdekammern
Boards of Appeal
Chambres de recours**

European Patent Office
D-80298 MUNICH
GERMANY
Tel. +49 (0) 89 2399-0
Fax +49 (0) 89 2399-4465

Case Number: T 1775/11 - 3.3.05

**D E C I S I O N
of Technical Board of Appeal 3.3.05
of 14 April 2015**

Appellant: PQ Silicas UK Limited
(Patent Proprietor) Bank Quay
4 Liverpool Road
Warrington
Cheshire WA5 1AQ (GB)

Representative: Dauncey, Mark Peter
Marks & Clerk LLP
1 New York Street
Manchester, M1 4HD (GB)

Respondent 1: Evonik Degussa GmbH
(Opponent 1) Rodenbacher Chaussee 4
63457 Hanau (DE)

Representative: Godemeyer Blum Lenze Patentanwälte
Partnerschaft mbB - werkpatent
An den Gärten 7
51491 Overath (DE)

Respondent 2: Grace GmbH & Co. KG
(Opponent 2) In der Hollerhecke 1
67545 Worms (DE)

Representative: van Heesch, Helmut Werner
Uexküll & Stolberg
Patentanwälte
Beselerstrasse 4
22607 Hamburg (DE)

Respondent 3: J.M. Huber Corporation
(Opponent 3) 1000 Parkwood Circle, Suite 1000
30339 Atlanta (US)

Representative: Wibbelmann, Jobst
Wuesthoff & Wuesthoff
Patentanwälte PartG mbB
Schweigerstrasse 2
81541 München (DE)

Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 8 June 2011
revoking European patent No. 1456125 pursuant to
Article 101(3) (b) EPC.**

Composition of the Board:

Chairman G. Raths
Members: H. Engl
 P. Guntz

Summary of Facts and Submissions

- I. European patent No. 1 456 125 was granted with 32 claims.

Independent claims 1 and 12 read as follows:

"1. An amorphous silica for use in a dental composition having a weight mean particle size in the range 3 to 15 μm with at least 90 per cent by weight of particles having a size below 20 μm , a Radioactive Dentine Abrasion (RDA) determined on an aqueous slurry of the silica powder of 100 to 220, a Pellicle Cleaning Ratio (PCR), when incorporated in a dental composition at 10 per cent by weight, greater than 85, the ratio of PCR to RDA being in the range 0.4 : 1 to less than 1:1 and having a Plastics Abrasion Value in the range 11 to 19."

"12. A dental composition comprising an amorphous silica according to claim 1, and an orally acceptable carrier."

The patent furthermore contains an independent claim for a process of preparation of an amorphous silica and a claim for the use of the amorphous silica according to claim 1, as an anti-blocking agent in a polymer composition.

- II. The granted patent was opposed by three opponents, invoking the grounds of opposition according to Article 100(a), (b) and (c) EPC. The opponents requested revocation of the patent in its entirety.

- III. The opposition division held that claims 1 and 19 of the main request contravened Article 123(2) EPC and that the patent did not meet the requirements of Article 83 EPC. The auxiliary request was also rejected and the patent thus revoked.
- IV. A notice of appeal was filed by the patentee (henceforth: the appellant).

Under cover of a letter dated 17 October 2011, the appellant submitted a statement of grounds for appeal and new claims as a main request and a first and a second auxiliary request. In this letter, the appellant also mentioned further sets of claims forming auxiliary requests three to six, without however appending clean copies of the claims as annexes. These claims were to be considered if the board decided to address in its decision not only the requirements of Articles 83, 84 and 123 EPC, but also matters of novelty and inventive step, without remitting the case to first instance.

- V. The independent claims of the said requests read as follows:

Main request:

"1. An amorphous silica suitable for use in a dental composition having a weight mean particle size in the range 3 to 15 μm with at least 90 per cent by weight of particles having a size below 20 μm characterised in that the amorphous silica has:

a) a Radioactive Dentine Abrasion (RDA) determined on an aqueous slurry of the silica powder of 100 to 220, and

b) a Pellicle Cleaning Ratio (PCR), when incorporated in a dental composition at 10 per cent by weight, greater than 85, wherein the dental composition used for the PCR measurement has, in addition to the amorphous silica, by weight, water at 27.6%, sorbitol at 30.8%, Sorbosil TC15 silica thickener at 11.0%, glycerine at 9.5%, polyethylene glycol (PEG 600) at 10%, tetrapotassium pyrophosphate at 2.0%, sodium lauryl sulphate at 2.0%, 50 weight% aqueous sodium hydroxide at 1.0%, flavour at 1.0%, sodium monofluorophosphate at 0.8%, sodium carboxymethyl cellulose at 0.6%, titanium dioxide at 0.5% and saccharin at 0.2%,

wherein the ratio of PCR to RDA is in the range 0.4 : 1 to less than 1 [*], and

c) a Plastics Abrasion Value in the range 11 to 19."

"12. A dental composition comprising an amorphous silica according to claim 1 and an orally acceptable carrier."

Claims 2 to 11 define preferred embodiments of the silica of claim 1, and Claims 13 to 18 define preferred embodiments of the dental composition of claim 12.

[*] interpreted by the board as "1:1"

First auxiliary request:

Claim 1 differs from claim 1 of the main request in that the term "Sorbosil TC 15" is deleted from the claim.

Claims 2 to 11 define preferred embodiments of the

silica of claim 1, and Claims 13 to 18 define preferred embodiments of the dental composition of claim 12.

Second auxiliary request:

"1. A dental composition comprising:

from 10 to 25% by weight of an amorphous silica suitable for use in a dental composition having a weight mean particle size in the range 3 to 15 μm with at least 90 per cent by weight of particles having a size below 20 μm , a Radioactive Dentine Abrasion (RDA) determined on an aqueous slurry of the silica powder of 100 to 220, a Plastics Abrasion Value in the range 11 to 19,

and an orally acceptable carrier,

wherein the Pellicle Cleaning Ratio (PCR), for the dental composition is greater than 85 and the ratio of PCR to RDA is in the range 0.4 : 1 to less than 1:1."

Claims 2 to 4 define preferred embodiments of the dental composition of claim 1.

VI. Oral proceedings before the board of appeal took place on 18 April 2015. The appellant had previously announced that it would not attend the oral proceedings.

VII. The arguments of the appellant may be summarized as follows:

The appellant refuted the arguments of the opposition division. The opposition division had disputed the sufficient disclosure of the claimed subject-matter not

because the application did not adequately explain to the skilled person how to make the silica and how to measure the PCR value required, but rather because it considered that the subject-matter of claim 1 as a whole could not be carried out by the skilled person, over the full claimed scope, without undue burden. It was not possible to identify on the basis of the information contained in the patent specification, without carrying out tests for each individual silica, which amorphous silicas, other than those exemplified, could reasonably be expected to fulfil the requirements set out in claim 1.

According to the appellant, by providing two working examples, the application provided a "best mode" of making the claimed silicas. Sufficient process details were given for making the silicas of Examples 1 and 2 having the characteristics set out in table 2. It was straightforward for the skilled person to modify said process parameters and to vary the silica characteristics from those of the examples to other ones falling within the claimed range.

The application described a process window, not a single process. Minor modifications to the process would lead to small variations in the characteristics of the silica obtained and so would enable the skilled person to make silicas over the full ranges claimed. These ranges were all narrow ranges for the parameters used to distinguish the claimed family of silicas.

In particular, the desired silicas were obtained by a modification of the process of D4 using particularly high shear input of at least 0.36 MJ/kg of SiO₂ throughout the simultaneous addition / reaction of silicate and acid. The resulting silica was defined in

terms of the parameters RDA and PAV, intrinsic to the silica, and PCR, achievable when the silica was used in toothpaste formulations. There was no need to provide a clear and exhaustive description since it was customary in the field of silicas to describe the products also by performance characteristics determined by the detailed structural characteristics of the silica which were in turn determined by the details of the process used to prepare the silica.

The appellant submitted that the parameters employed to define pellicle removal capability for a silica, the damage to teeth by scratching and the abrasivity of a silica were known in the field of dental abrasives, and their use was well established at the priority date of the opposed patent.

It was no more of a "burden" to the skilled person to measure in vitro performance parameters than it was for him or her to measure structural parameters, such as surface area or pore volume. If it was acceptable to claim a silica defined by particle size, surface area, pore volume and the like, then it should also be considered as acceptable to use characteristics such as RDA, PCR, or PAV to define a silica. The methods of measurement of these parameters were set out in the opposed patent and were well defined.

Hence the claims of the main request met the requirements of Article 83 EPC. Essentially the same arguments applied to the subject-matter claimed in the auxiliary requests.

VIII. Summary of the arguments of the respondents:

On insufficiency of disclosure, the respondents pointed

out that the claimed silicas were defined by six parameters, some of them unusual in the field. There was a lack of guidance as to how to select silicas, other than those specifically disclosed by way of example, meeting the claimed parameters. The skilled person would be left without guidance as to how to prepare other types of amorphous silica falling within the scope of the claim. There was no teaching as to how the process parameters had to be selected in order to have the desired effects on PCR, RDA, PVA and PCR/RDA values. The skilled person thus had to resort to trial and error experimentation amounting to carrying out a research programme, what was an undue burden, contrary to Article 83 EPC.

Further arguments concerned lack of novelty and inventive step.

IX. Requests

The appellant requested that the contested decision be set aside and the European patent be maintained in amended form on the basis of the claims of the main request, or in the alternative, the claims of the first and second auxiliary requests, all filed with the statement of grounds of appeal.

The respondents requested that the appeal be dismissed.

Reasons for the Decision

1. Sufficiency of disclosure (Article 83 EPC)

1.1 Statutory law and jurisprudence

Article 83 EPC stipulates that the application shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

According to the jurisprudence of the Boards of Appeal of the EPO, for making a case of insufficiency of disclosure, it is necessary to identify *gaps in information* resulting either from limitations in teaching or a lack of guidance in general, or a lack in guidance in case of failures, or the impossibility to verify parameters, or purpose-related instructions or the absence of criteria for selection rules.

The question then to be answered is whether the skilled person with his common general knowledge can remedy any such defects, or whether the consequences of the information gaps result in an undue number of experiments to be performed ("undue burden", "research programme") (see T 32/85, of 5 June 1986).

1.2 Present case

The patent in suit claims a class of amorphous silicas which are inter alia suitable for use in dental compositions, such as a toothpaste. The silicas are characterized by a combination of properties which include weight mean particle size, a Radioactive Dentine Abrasion (RDA) value, a Plastics Abrasion Value (PAV), a Pellicle Cleaning Ratio (PCR), measured in a toothpaste formulation as defined in the claims, and a

ratio of PCR to RDA. Some of these properties are observable on the amorphous silicas as such, for instance the mean particle size, others indirectly from the performance of test compositions comprising the amorphous silica (PCR).

The amorphous silicas may be prepared by precipitation from aqueous sodium silicate solution and acid (e.g. sulfuric acid), under especially vigorous mixing. However, the claims are not limited to silicas prepared via this route.

1.3 Parameters and measurement methods

(a) The board accepts, to the benefit of the appellant, that the parameters used in the claims for defining the claimed silicas, namely pellicle removal capability (PCR) for a silica, the damage to teeth by scratching and the abrasivity of a silica (RDA), and PAV (plastics abrasion value), were known in the field of dental abrasives.

(b) The methods to determine these values are clearly disclosed in the opposed patent (see paragraphs [0057] to [0074]).

1.4 Incomplete teaching for carrying out the invention

As a rule, to satisfy the requirement of Article 83 EPC, at least one way of enabling the person skilled in the art to carry out the invention must be disclosed, this being sufficient only if it allows the invention to be performed in the whole range claimed, covering substantially all embodiments falling within the ambit of the claims. This principle has been confirmed by numerous decisions of the Boards of Appeal (see for

instance those cited in "Case Law of the Boards of Appeal of the EPO", 7th Edition 2013, page 309, chapter 4.4).

The respondents argued that the opposed patent was deficient in this respect.

1.5 Information gap in examples 1 and 2 of the patent in suit

The patent in suit contains two working examples. The experimental details thereof are summarised in Tables 1 and 2. However, it is observed that the crucial process parameter of energy input during mixing with a high shear Silverson mixer is only defined by its lower limit (0.36 MJ/kg). The actual energy input employed in the examples is not reported in Table 1.

This lack of disclosure was, in the respondents' views, all the more severe as the appellant itself argued that the claimed amorphous silica was obtainable by a modification of the process of D4, wherein the distinguishing process feature was the use of a particularly high shear input throughout the simultaneous addition/reaction of silicate and acid (see appeal brief, page 5, third complete paragraph). The respondents concluded that the examples could not be reworked without at first determining the appropriate amount of mixing shear energy.

1.6 Manufacturing information gap

The claims encompass a relatively wide class of amorphous silicas which are exclusively characterised by product parameters. In such a case, there should have been provided a clear and complete teaching how to

obtain the desired silicas, be it in the form of reproducible working examples as a starting point, or of other suitable general information. In the present case, the two working examples do not sufficiently describe the crucial mixing step, in spite of the importance attributed in the description to the amount of shear energy to be employed in the precipitation process.

The question arises of whether this information gap can be filled by the skilled person's general common knowledge and by routine experimentation. To be sure, there is limited guidance by the two examples and the description as regards the necessary lower limit of energy input (0.36 MJ/kg) during mixing. Based on this information, useful levels of shear energy input may in practice be found by following the examples and gradually increasing the mixing power from the minimum shear. Therefore the board accepts, to the benefit of the appellant, that the examples of the opposed patent, can be reworked without undue burden, despite the above mentioned information gap.

1.7 Feasibility over the whole ambit of the claims

However, the opposed patent is also deficient in another respect. In accordance with the case law, the disclosure of one way of performing the invention, for instance by way of examples, is only sufficient if it allows the invention to be carried out by the skilled person over the whole ambit of the claims. This must be possible without any inventive effort and undue burden, taking into account the original application as a whole and the general common knowledge of the skilled person. In the present case, the board answers this question in the negative, for the following reasons.

The data in Table 1 show that the preparation conditions of two working examples differ from each other by at least 5 parameters (i.e. water volume, silicate ratio, silicate volume, acid volume, temperature, and possibly shear energy input). Under these circumstances it is impossible to deduce which of the several simultaneous modifications in the processes of preparation were responsible for the differences found in the silicas so obtained (see Table 2). These silicas differ considerably in oil absorption (79 and 139 ml/100g, respectively), BET surface (64 and 252 m²/g, respectively), RDA (200 and 133, respectively) and tapped and loose bulk densities (see Table 2). However, they exhibit practically the same PCR value at 10% loading in toothpaste Formulation A (96 vs 93).

Based on these examples and the relevant parts of the specification, the skilled person is not taught how to obtain silicas having substantially different PCRs, for instance closer to the lower end point of 85 stated in the claim for a 10% dental composition. No information is available how to modify the process in order to obtain RDA values other than those exemplified (200 and 133) and how the process conditions determine the interaction between the various parameters characterising the claimed silicas. It is not plausible that essentially the whole host of claimed silicas may be obtained only by modifying the mixing intensity (shear energy input).

In summary, the skilled person can derive no useful guidance from the two examples as to how the process of preparation could be modified in order to obtain silicas having properties covering the whole width of the claims. The situation resembles the one aptly

denoted as an invitation to carry out a research programme. See decisions T 435/91 (OJ EPO 1995, 188; Reasons 2.2.1) and T 809/07 (of 15 April 2010, Reasons 3.2).

1.8 Lack of guidance

It must also be observed that some of the tests for determining the characterising parameters may be known and usual in the field of dental abrasives, yet are considerably time-consuming and elaborate.

- The RDA test for instance involves the irradiation of extracted human teeth with a neutron flux and subjecting it to a standard brushing regime. The radioactive phosphorus removed from the dentin in the roots of the teeth is used as an indication for the abrasive action of the dentifrice containing the amorphous silica under examination (see paragraph [0061] of the specification).

- The PCR test uses bovine permanent central incisors, cut to obtain specimens which are then smoothed and polished and immersed for 4 days in a staining broth replenished twice a day.

- The dentifrice containing the test silica at 10% by weight, is applied under 800 double strokes of a soft nylon toothbrush and the specimens are assessed before and after the brushing exercise (see paragraph [0064] of the specification).

The respondents argued convincingly that these highly specific test procedures might be usual in the field of abrasive silicas developed especially for toothpaste applications, but are not common in other important

fields of application of finely divided amorphous silicas (e.g. as fillers, thickeners, absorbents et cetera). The present claims are however not restricted to amorphous silicas in toothpastes or as abrasives. Therefore, so the respondents' argument, it was extremely burdensome for the skilled person to repeat these experiments on a trial and error basis, without proper guidance as to which results could be expected.

The board considers that under such circumstances, it would have been indispensable to disclose in a complete and systematical manner which relations exist between the values of RDA, PCR, PVA and PCR/RDA, and how these parameters could be adjusted to desired values within the claimed ranges.

In other words, the patent in suit lacks a technical concept fit for generalisation which makes the host of silicas encompassed by the definition of the claims available to the skilled person without undue experimentation.

- 1.9 The requirements of Article 83 EPC are thus not met for the main request.

This objection applies *mutatis mutandis* also to the claims according to the first and second auxiliary requests which recite the same product parameters and ranges.

2. Further auxiliary requests

In the appeal brief, the appellant referred to further requests (third to sixth auxiliary requests). However, these requests were not annexed to the grounds of appeal, but only summarily set out as regards the

various proposed amendments to the claims.

The board understands that these requests were filed for consideration only in the event that the board deemed one of the main, first and second auxiliary requests to meet the requirements of Rule 80 and Article 83, 84 and 123 EPC, and decided to address the questions of novelty and inventive step, without remitting the case to the department of first instance.

Since however the claims of the main, first and second auxiliary requests were found not to meet the requirements of Article 83 EPC, this procedural condition is not met. The third to sixth auxiliary requests thus need not be considered by the board for this reason alone and irrespective of their formal deficiencies.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



L. Malécot-Grob

G. Rath

Decision electronically authenticated