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**Datasheet for the decision
of 18 February 2025**

Case Number: T 0329/23 - 3.3.07

Application Number: 14738952.2

Publication Number: 3013306

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A61K6/818, A61K6/822

Language of the proceedings: EN

Title of invention:
NANOCRYSTALLINE ZIRCONIA AND METHODS OF PROCESSING THEREOF

Patent Proprietor:
Ivoclar Vivadent, Inc.

Opponent:
Solventum Intellectual Properties Company /
Solventum Germany GmbH

Headword:
Nanocrystalline zirconia / IVOCALAR VIVADENT

Relevant legal provisions:
EPC Art. 100(b), 83

Keyword:
Sufficiency of disclosure - (no)



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Case Number: T 0329/23 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 18 February 2025

Appellant:
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Decision under appeal:

**Interlocutory decision of the Opposition
Division of the European Patent Office posted on
20 December 2022 concerning maintenance of the
European Patent No. 3013306 in amended form.**

Composition of the Board:

Chairwoman	J. Lécaillon
Members:	E. Duval
	L. Basterreix

Summary of Facts and Submissions

I. The appeals were filed by the patent proprietor and the joint opponents against the interlocutory decision of the opposition division finding that, on the basis of auxiliary request 4, the patent met the requirements of the EPC.

II. The decision was based on:

- the patent as granted as main request,
- auxiliary request 1 filed on 20 September 2021,
- auxiliary request 2 filed during the oral proceedings before the opposition division,
- auxiliary request 3 filed (as auxiliary request 2) on 20 September 2021, and
- auxiliary request 4 filed during the oral proceedings.

III. Claim 1 of the main request, i.e. the patent as granted, related to:

"A zirconia dental ceramic comprising:
predominantly tetragonal zirconia with less than 15% monoclinic and cubic phases combined;
at least 95% of all grains by volume within the range of 10 nm to 300 nm;
a density of at least 99.5% of theoretical density; and exhibiting opalescence."

IV. The following document was cited, among others, in the appealed decision:

D8: EP 3 088 373 A1

V. According to the decision, the main request and auxiliary requests 1-3 were rejected for lack of novelty or inventive step. Auxiliary request 4 was found to meet the requirements of the EPC. Regarding sufficiency of disclosure, the opposition division decided as follows:

(a) Firstly, to determine the parameter of claim 1 relating to grain size by volume, the intercept method according to ASTM E112 would be used. Although ASTM E112 related to the characterization of two-dimensional grain size sections, the person skilled in the art would measure several planar sections in order to infer the grain size in the total volume.

(b) The second parameter of claim 1, namely the relative density, would be calculated by determining the density of the sintered article by the Archimedes method using water as the immersion medium and dividing by a theoretical density value set to 6.08 g/cm^3 based on paragraph [0080] of the application as filed.

Hence, both the grain size distribution and the relative densities were sufficiently disclosed.

VI. With their statement setting out the grounds of appeal, the appellant - patent proprietor defended their case on the basis of the patent as granted as the main request, and filed auxiliary requests 1-10.

In claim 1 of each of auxiliary requests 1-10, as in claim 1 of the main request, the zirconia dental ceramic was defined by "at least 95% of all grains by volume within the range of 10 nm to 300 nm", by "a

density of at least 99.5% of theoretical density", and by its opalescence.

VII. The Board set out its preliminary opinion in a communication under Article 15(1) RPBA.

VIII. Oral proceedings were held before the Board by videoconference.

IX. The requests of the parties were the following:

(a) The appellant - patent proprietor requests that the decision under appeal be set aside and that the patent be maintained as granted, or, alternatively, that the patent be maintained on the basis of one of auxiliary requests 1-10 filed with the grounds of appeal.

(b) The appellants - opponents request that the decision under appeal be set aside and that the patent be revoked.

The appellants - opponents further request that none of the auxiliary requests 7-10 be admitted.

X. The arguments of the appellants - opponents may be summarised as follows:

(a) Regarding the grain size distribution, claim 1 contained no hint which measurement method should be used. The description suggested several options, namely ASTM E112, SEM or XRD. The values reported in Table 2 using SEM or XRD varied by a factor of about 2. ASTM E112 mentioned different methods for determining the average grain size, and stated that the test methods shown therein referred to the

characterization of two-dimensional grain size sections, whereas in claim 1 a grain size by volume was claimed. This feature was thus not enabled.

- (b) The patent did not teach how to determine the theoretical density and thus the relative density for materials other than 3 mol% yttria containing zirconia. Considering that paragraph [0041] belonged to the example section of the patent, the person skilled in the art would understand that the density of 6.08 g/cm^3 cited therein was to be used only for the materials used in the examples. The use of this fixed value for the theoretical density would lead to results which did not technically make sense.

Accordingly, the criteria of sufficiency of disclosure were not met.

XI. The appellant - patent proprietor's arguments may be summarised as follows:

- (a) Having regard to grain size, the patent indicated that the intercept method according to ASTM E112-12 was used to determine the average grain size and the grain size distribution. The claimed grain size per volume could be inferred from the ASTM E112-12 measurement, or determined by measuring several planar sections.
- (b) Regarding relative density, the patent clearly indicated that relative density of claim 1 was calculated on the basis of a theoretical density value of 6.08 g/cm^3 .

Reasons for the Decision

1. Main request (patent as granted), sufficiency of disclosure
 - 1.1 Claim 1 of the main request mandates that the zirconia dental ceramic meets the following conditions:
 - at least 95% of all grains by volume within the range of 10 nm to 300 nm;
 - a density of at least 99.5% of theoretical density; and
 - exhibiting opalescence.

For the following reasons, the Board comes to the conclusion that both the grain size distribution and the relative density are essential for the achievement of the claimed effect of opalescence, and that the indetermination of the measurement/calculation methods for both parameters leads to a lack of sufficient disclosure.

- 1.2 Claim 1 firstly defines a grain size distribution, i.e. mandates that at least 95% of all grains by volume are within the range of 10 nm to 300 nm.
 - 1.2.1 Several methods for the determination of average grain sizes are mentioned in the patent, namely the intercept method according to ASTM E112-12 (see paragraphs [0019] and [0044]), ASTM E112 or EN 623-3 (see paragraph [0026]), SEM or XRD (see table 2). Table 2 in particular shows large variations in the measured grain sizes for the same material depending on the method used (XRD vs SEM), by a factor of two. The appellant - patent proprietor submitted that, in table 2, SEM was used as imaging technique, and that the grain sizes

were still assessed, based on the SEM imaging results, using the ASTM E112 method. However, it remains that several methods with significantly different results are mentioned in the description.

The appellant - patent proprietor holds that the intercept method according to ASTM E112-12 would be used to determine the average grain size *and* the grain size distribution. The Board does not concur.

- 1.2.2 Firstly, the ASTM E112-12 method is only mentioned in the patent as a method for measuring an average grain size, i.e. a single value for the sample. This is explicit in the wording of paragraphs [0019], [0026] and [0044]. In contrast, claim 1 defines a grain size distribution, i.e. the proportion of grains whose *individual* sizes are within the claimed range. An average grain size provides no information on grain size distribution. The appellant - patent proprietor did not substantiate their claim that the same ASTM E112 method can also be used for grain size distribution.
- 1.2.3 Secondly, the ASTM E112 standard states explicitly that its test methods "deal only with determination of planar grain size, that is, characterization of the two-dimensional grain sections revealed by the sectioning plane. Determination of spatial grain size, that is, measurement of the size of the three-dimensional grains in the specimen volume, is beyond the scope of these test methods" (see the appellants - opponents' grounds of appeal, page 11). In contrast, claim 1 does not define a planar grain size, but a distribution of grain sizes by volume.

The appellant - patent proprietor counters that the planar method must allow to infer a three-dimensional size and therefore also a volume distribution. Analogously, the opposition division had taken the view that the person skilled in the art knows that it is customary to measure several planar sections for determining the grain size in order to infer about the grain size in the total volume. However, none of these allegations are supported by the ASTM E112 itself, which is explicitly limited to the determination of planar grain size, i.e. two-dimensional grain sections revealed by the sectioning plane. These allegations are also not supported by the disclosure of the patent, which provides no indication that the ASTM E112 standard should be used, or is even suitable, for determining the claimed grain size distribution by volume. The patent contains no instance of such a determination using several planar measurements or otherwise. In fact, the patent contains no measurement of any grain size distribution by volume for any of the exemplified sintered materials. Only (average) grain sizes are reported for the exemplified ceramics. In this sense, the patent does not disclose at least one way of carrying out the invention.

- 1.2.4 The relevance of this indetermination of the measurement method and variability of the results for the issue of sufficiency of disclosure was not contested. The Board considers that, under the present circumstances, this indetermination is not merely an issue of defining the boundaries of the claim. The patent postulates that the specific grain size distribution, among other parameters, is responsible for the opalescence properties of the zirconia of the invention (see e.g. [0035]). Paragraph [0019] even states "The desired level of opalescence exists only

for specific combination of porosity, and pore/grain size distributions". Since claim 1 requires the zirconia dental ceramic to exhibit opalescence, the achievement of this property across the range of volume grain size distributions defined by claim 1 is a requirement for sufficiency of disclosure of the claimed invention. Considering the entire lack of information as to the method and the large variation reported in table 2, this requirement is not met.

- 1.3 Claim 1 further defines a relative density, i.e. requires the zirconia to have a density of at least 99.5% of theoretical density. The calculation of this parameter thus requires a determination of the theoretical density of the zirconia at hand.

The appellants - opponents submitted that different kinds of zirconia materials have different theoretical densities, depending on e.g. crystal phase content, additives, or stabiliser content. This is confirmed by D8, which reports theoretical densities ranging from 6.019 g/cm³ to 6.095 g/cm³ (see table 1, paragraph [0035]). According to the appellants - opponents, the patent does not teach how to calculate the theoretical density for zirconia materials other than the exemplified 3 mol% yttria (Y₂O₃) stabilized zirconia. The opposition division found that there is indeed no teaching about how to calculate the theoretical density in the patent in suit (see the appealed decision, point 2.13). This finding is not contested by the appellant - patent proprietor.

The appellant - patent proprietor however contends that the relative density of claim 1 would be calculated on the basis of a fixed theoretical density value of 6.08 g/cm³ following paragraph [0041] of the patent:

"Relative density, calculated using a theoretical density value of 6.08 g/cm^3 , is usually $> 99.5\%$ in fully sintered articles in the current invention."

The appellant - patent proprietor's argument supposes that claim 1, which uses the expression "theoretical density" and does not specify a fixed value, be construed in a manner which departs its normal reading. The question as to whether the description and figures may be consulted when interpreting the claims to assess patentability is currently the topic of referral G 1/24 pending before the Enlarged Board of Appeal. The present Board however considers that, irrespective of the answer to be given, the present description does in any case not contain a generally applicable definition, or similar information, for the expression "theoretical density". Paragraph [0041] belongs to the preamble of the example section of the patent. The examples use 3 mol% yttria stabilized zirconia (see paragraph [0045]), or, in the case of the comparative example 7 (none of which satisfy the claimed relative density feature), 0 mol% yttria containing zirconia (see paragraph [0074]). There is no indication in the patent that the density of 6.08 g/cm^3 cited in paragraph [0041] is destined to apply to materials other than the examples and be generally applicable to all zirconia materials covered by claim 1. Furthermore, the use of this fixed value would, as acknowledged in the appealed decision (see points 2.14 and 2.15), lead to the surprising outcome that materials with high density have relative densities over 100%, and negative porosities (which is an essential parameter for obtaining the claimed opalescence, see 1.2.4 above). Consequently, the Board considers that, even if the skilled person were to turn to the description to interpret "theoretical density",

they would not construe this expression as referring generally to the fixed value of 6.08 g/cm^3 mentioned in paragraph [0041], because this passage is not of general application and leads to inconsistent results for some materials.

1.4 Accordingly, the criteria of sufficiency of disclosure are not met.

2. Auxiliary requests 1-10

Claims 1 and 15 in each of auxiliary requests 1-10 contain the same features pertaining to grain size distribution by volume, relative density and opalescence. The same conclusion consequently applies. None of the auxiliary requests 1-10 meet the requirement of sufficiency of disclosure. In view of this conclusion, it is not necessary to address the appellants - opponents' objection against the admittance of auxiliary requests 7-10.

Order

For these reasons it is decided that:

The decision under appeal is set aside.

The patent is revoked.

The Registrar:

The Chairwoman:



B. Atienza Vivancos

J. Lécaillon

Decision electronically authenticated