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**Datasheet for the decision
of 10 November 2017**

Case Number: T 2076/13 - 3.3.07

Application Number: 06021966.4

Publication Number: 1854445

IPC: A61K6/00, A61K6/08, G01N11/06,
G01N13/02

Language of the proceedings: EN

Title of invention:

Method and means for infiltrating enamel lesions

Patent Proprietor:

Charité - Universitätsmedizin Berlin

Headword:

Means for infiltrating enamel lesions / CHARITE'

Relevant legal provisions:

EPC Art. 100(c), 100(b)
EPC R. 84(2)

Keyword:

Amendments - allowable (yes)
Grounds for opposition - insufficiency of disclosure (no)
Remittal to the department of first instance (yes)

Decisions cited:

T 0593/09, T 0608/07, T 2290/12, T 0385/13, T 1988/13,
T 1414/08



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Case Number: T 2076/13 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 10 November 2017

Appellant: Charité - Universitätsmedizin Berlin
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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 26 July 2013
revoking European patent No. 1854445 pursuant to
Article 101(3) (b) EPC.**

Composition of the Board:

Chairman D. Boulois
Members: A. Uselli
P. Schmitz

Summary of Facts and Submissions

- I. European patent No. 1 854 445, based on European application 06021966.4, was granted on the basis of 11 claims.

Claim 1 read as follows:

"1. A kit for infiltrating enamel, comprising:

a) a conditioner based on a gel comprising 5-30% (w/w) of hydrochloric acid, preferably 5-15% (w/w) of hydrochloric acid; and

b) an infiltrant comprising a low viscous light curing resin, the infiltrant having a penetration coefficient of >50 cm/s, using the following equation:

$$PC = (\gamma \cos \theta / 2\eta)$$

wherein:

PC refers to the penetration coefficient; γ refers to the surface tension of the liquid resin (to air);

θ refers to the contact angle of the liquid resin (to enamel); and η refers to the dynamic viscosity of the liquid resin".

- II. Two oppositions were filed against the patent on the grounds that its subject-matter lacked novelty and inventive step, it was not sufficiently disclosed and it extended beyond the content of the application as filed.

The following documents were among those cited during the opposition procedure:

D22: Acta Odont. Scand., 35, 175-182, 1977

D23: Dissertation of S.C. Ehrardt, 2008

III. By decision posted on 26 July 2013 the patent was revoked. The decision was based on the patent as granted as the main request and on 18 auxiliary requests. The opposition division held that claim 1 of the patent contained subject-matter extending beyond the content of the application as filed and was not sufficiently disclosed.

Concerning Article 100(c) EPC, the opposition division observed that component b) of granted claim 1 was an infiltrant containing a "low viscous" (i.e. low-viscosity) light-curing resin, this resin not having any further limitations. The disclosure in the original application concerning this low-viscosity light-curing resin was always limited by the indication that said entity had a penetration coefficient of more than 50 cm/s. Thus, claim 1 of the patent also covered infiltrants containing low-viscosity light-curing resins having a penetration coefficient of less than 50 cm/s, thereby extending beyond the content of the original disclosure.

As to the requirement of sufficiency of disclosure, the opposition division took the view that the skilled person did not know which temperature to use when measuring the contact angle and the surface tension. Determining these parameters was necessary in order to calculate the penetration coefficient of the infiltrant which was a feature of claim 1. Therefore the disclosure of the patent did not enable the skilled person to carry out the invention.

The same conclusions applied to the subject-matter of claim 1 of auxiliary requests 1 to 16. Auxiliary requests 17 and 18 were not admitted because they did

not *prima facie* overcome the problem of insufficiency of disclosure.

- IV. The patent proprietor (appellant) filed an appeal against that decision. With the statement setting out the grounds of appeal filed on 5 December 2013 it submitted 16 auxiliary requests and the following document:

D101: Experimental report of Dr Swen Neander

- V. The appellant's arguments can be summarised as follows:

(a) Article 100(c) EPC

Component b) of the kit defined in claim 1 of the patent had a basis in original claim 8. This claim referred to an infiltrant having a penetration coefficient of more than 50 cm/s. It was clear, for instance from the last paragraph of page 2 of the application as filed, that low-viscosity light-curing resins were an essential element of the infiltrants. Hence, the skilled reader would have understood that the infiltrant of original claim 8, having a penetration coefficient of more than 50 cm/s, also comprised a low-viscosity light-curing resin. This provided a basis for component b) of claim 1.

(b) Article 100(b) EPC

The penetration coefficient was a parameter calculated on the basis of three measured values, namely the surface tension, the contact angle and the dynamic viscosity. Although the description of the patent did not indicate the temperature for measuring the surface tension and the contact angle, the skilled person would have understood that these parameters had to be measured at the same temperature at which the

measurement of the viscosity was made, i.e. 25°C as reported in paragraph [0025] of the patent. This could have been easily confirmed by repeating the examples of the patent and comparing the results with the values reported in Table 2. Furthermore, variations in the temperature at which the three parameters were measured did not result in major variations in the penetration coefficient. A minor uncertainty in the determination of the penetration coefficient could cause some ambiguity in the definition of the boundaries of the claim. However, according to the case law of the boards of appeal, this was an issue of clarity rather than sufficiency of disclosure.

- VI. In their replies to the appellant's statement of grounds of appeal, the opponents maintained that claim 1 of the patent contained subject-matter extending beyond the content of the application. As to the requirement of sufficiency of disclosure, they observed *inter alia* that the patent did not provide any information as to the temperature for determining the surface tension and the contact angle. According to D23, variations in the temperature had a major impact on the value of the penetration coefficient. Hence, the requirement of sufficiency of disclosure was not met.
- VII. By letters submitted on 6 April 2016 and 7 March 2016 respectively, opponent 1 and opponent 2 withdrew their oppositions.
- VIII. The appellant's main request was to set aside the decision of the opposition division, to find that the patent as granted fulfils the requirements of Articles 123(2) and 83 EPC and to remit the case to the opposition division so as to provide the parties with

an opportunity to have the remaining objections raised in the oppositions decided in two instances.

Reasons for the Decision

Admissibility of document D101

1. Document D101 is an experimental report that the appellant submitted with its statement setting out the grounds of appeal. The main purpose of the experiments disclosed therein is to show that variations in temperature have a minimal impact on the value of the surface tension.

1.1 The filing of D101 is therefore a reaction on the part of the appellant to the opposition division's conclusion that the requirement of sufficiency of disclosure was not met since no information was given in the patent as to the temperature for measuring the surface tension and the contact angle.

The Board sees no reason why the appellant should have filed document D101 during the first-instance proceedings. In this respect it also notes that, in the communication annexed to the summons to oral proceedings, the opposition division did not express the view that the absence of information as to the conditions for measuring the surface tension and the contact angle resulted in a problem of insufficiency of disclosure.

For these reasons the Board decides to admit document D101 into the appeal proceedings.

Patent as granted

2. Article 100(c) EPC

2.1 Claim 15 of the application as originally filed reads:

"A kit for infiltrating enamel, comprising:
(a) a conditioner comprising hydrochloric acid; and
(b) an infiltrant."

The kit defined in claim 1 of the patent in suit is based on original claim 15 in combination with original claims 17 and 8, as explained in the following paragraphs.

2.1.1 Original claim 17 depends on claim 15 and indicates that the conditioner "is based on a gel comprising about 1-30% (w/w) of hydrochloric acid, preferably about 5-15% (w/w)". This claim therefore provides a basis for the percentage of hydrochloric acid in component a) given in claim 1 as granted.

2.1.2 The definition of component b) in claim 1 as granted is based on original claim 8. This claim relates to two alternative infiltrants:

- a) an infiltrant having a penetration coefficient greater than 50 cm/s and
- b) an infiltrant comprising a low-viscosity light-curing resin having a penetration coefficient greater than 50 cm/s.

Although it may not be clear from the wording of claim 8, the infiltrant according to alternative a) also contains a curable resin. As explained in the "background of the invention" in the original

application, an infiltrant is a composition capable of penetrating the enamel lesions and infiltrating the tiny pores within the lesions. At the same time the infiltrant must provide a hard material that gives mechanical support to the enamel (page 2, lines 29 to 32). This effect can be achieved by the presence in the composition of a curable component which is capable of hardening after penetrating the enamel lesions (e.g. under the effect of light). A literal interpretation of alternative a) as covering an infiltrant that does not contain any component capable of providing a hard material would be technically meaningless. Indeed all the 66 infiltrants listed in Table 2 of the patent contain a curable resin and no reference can be found in the original application to an infiltrant that does not contain a curable resin.

Thus, the skilled reader would understand that both alternatives a) and b) of claim 8 relate to infiltrants containing a curable resin. The difference between the two alternatives is that in case a) the whole infiltrant must have a penetration coefficient greater than 50 cm/s (and the penetration coefficient of the curable resin may be greater, equal or lower than 50) whereas in case b) the major component of the infiltrant (i.e. the resin) must satisfy the requirement of having a penetration coefficient greater than 50 cm/s.

In claim 1 of the patent the infiltrant has been limited to the first of the two alternatives covered by original claim 8 (alternative a)) with the explicit indication that the infiltrant contains a light-curing resin. The indication "light curing" finds support in various parts of the original application, such as page 19, ninth paragraph, which states that the infiltrant

is preferably cured by light-induced polymerisation. Moreover, in all the 66 products listed in Table 2, the resin is light-cured (original application, page 30, lines 12 to 14).

The property of the resin being "low viscous" (i.e. low-viscosity) finds support in various parts of the original application, e.g. page 15, lines 2 and 3 or page 11, line 13.

2.2 In view of the above, the Board concludes that the amendments leading to claim 1 have a basis in the application as filed. Thus, the ground under Article 100(c) EPC does not preclude the maintenance of the patent as granted.

3. Sufficiency of disclosure

3.1 The penetration coefficient of the infiltrant, which is a feature of claim 1, is calculated from the values of three parameters, namely the surface tension, the contact angle and the dynamic viscosity (see equation in claim 1 and paragraphs [0043] to [0046]). The measurement of these parameters is therefore essential for carrying out the invention defined in claim 1.

The opposition division held that the requirement of sufficiency of disclosure was not met since the patent did not indicate at which temperature the surface tension and the contact angle were to be measured.

3.2 The patent indicates in paragraph [0072] that the dynamic viscosity is obtained by multiplying the kinematic viscosity with the density. The same paragraph states that the kinematic viscosity is measured at 25°C.

The Board agrees with the appellant that, although the patent does not disclose the temperature at which the surface tension and the contact angle are measured, the skilled person would assume that this temperature is very likely the same temperature used for measuring the kinematic viscosity. As mentioned above, the penetration coefficient depends on three parameters, namely the surface tension, the contact angle and the dynamic viscosity. The most straightforward approach that a skilled person would follow in order to determine the penetration coefficient of a given substance would be to measure these three parameters at the same temperature. Thus, in the absence of any indication to the contrary, the skilled person trying to perform the invention of claim 1 would assume that, just like the viscosity, the surface tension and the contact angle are very likely to be measured at 25°C. Furthermore, it would be easy for him to verify whether this hypothesis is correct. Table 2 of the patent discloses the surface tension, the dynamic viscosity and the contact angle of 66 different infiltrants. Thus, it would be possible for the skilled person to prepare at least some of these infiltrants, to measure the parameters at 25°C and verify whether the values obtained correspond to those reported in the table. In this context it is noted that the preparation of the infiltrants listed in Table 2 simply requires mixing a few commercially available substances. Document D101 shows that the surface tension of products 4 and 28 of Table 2 has indeed been determined at 25°C. The opponents did not submit any kind of evidence in this respect.

Thus, the skilled person would be able to identify without undue burden the temperature at which the

surface tension and the contact angle are to be measured. For this reason alone, the Board cannot come to the same conclusion as the opposition division that the patent does not meet the requirement of sufficiency of disclosure since it does not specify the temperature at which the surface tension and the contact angle are measured.

- 3.3 Regardless of the considerations set out above, the Board observes that deficiencies arising from the presence in a claim of an ambiguously defined parameter or a parameter that could be measured by different methods or under different conditions leading to different values do not necessarily result in a problem of insufficiency of disclosure.

On this issue, in T 593/09 the board held that "*[w]hat is decisive for establishing insufficiency within the meaning of Article 83 EPC is whether the parameter, in the specific case, is so ill-defined that the skilled person is not able, on the basis of the disclosure as a whole and using his common general knowledge, to identify (without undue burden) the technical measures (eg selection of suitable compounds) necessary to solve the problem underlying the patent at issue*" (Reasons, point 4.1.4).

Along the same line, in T 608/07 the board stated that "*for an insufficiency arising out of ambiguity it is not enough to show that an ambiguity exists, eg at the edges of the claims. It will normally be necessary to show that the ambiguity deprives the person skilled in the art of the promise of the invention*" (Reasons, point 2.5.2).

The same approach has been followed in various other decisions such as T 385/13 (Reasons, point 3.4.3) and T 1988/13 (Reasons, point 1.2).

Furthermore, in a number of decisions the boards have held that when the presence of an ill-defined parameter merely generates some uncertainty in the definition of the boundaries of the claim, with the effect that the skilled person would not know whether he is working within or outside the scope of the claims, there is normally a problem of clarity rather than insufficiency (see e.g. T 593/09 and T 608/07, *supra*, T 2290/12, Reasons, point 3.1 and T 1414/08, Reasons, point 8).

This Board agrees with the rationale of these decisions.

- 3.4 In the present case the opponents have not produced any evidence or a convincing argument that, as a consequence of the alleged deficiency in the definition of the surface tension and of the contact angle, the skilled person would be deprived of the promise of the invention because he would not be able to select the appropriate infiltrants. In this respect the Board observes that paragraphs [0019] and [0020] of the patent provide general information on the composition of the infiltrants and Table 2 discloses several specific examples of suitable infiltrants.

There is furthermore no evidence that, in the present case, variations in the temperature at which the surface tension and the contact angle are measured have a major impact on the value of the penetration coefficient. The opponents referred in this regard to a passage of D23 (paragraph bridging pages 45 and 46) according to which, in a study dating back to 1975, it

was observed for a specific infiltrant that the penetration coefficient at 37°C was 2.5 times greater than the value determined at 25°C. In this regard the Board notes that the same passage explains that this effect was mainly due to the diminution of the viscosity with the increase in temperature. However in the present case the viscosity is to be determined at a fixed temperature, namely 25°C. Thus, D23 does not indicate that measuring the surface tension and the contact angle at different temperatures results in strong variations in the penetration coefficient.

Moreover, Table 1 of the experimental report submitted by the appellant (document D101) shows that there is minimal variation in the surface tension in the range 20° to 37°C. As to the contact angle, the Board observes that paragraph [0074] of the patent explains that variations in its value have a limited impact on the penetration coefficient as, in accordance with the formula in claim 1, the contact angle affects the penetration coefficient only proportionally to its cosine. Furthermore, document D22 shows that in some acrylic resins containing the same monomers as the resins listed in table 2 of the patent, the cosine of the contact angle is approximately inversely proportional to the surface tension (page 179, paragraph "Contact angle", and Figure 3). As both the surface tension and the cosine of the contact angle are multiplied in the numerator of the formula in claim 1 any variations in their values would tend to cancel each other out so that the combined influence on the penetration coefficient of the contact angle and the surface tension at varying temperatures would be very limited.

3.5 In summary, on the basis of the evidence and arguments submitted by the parties, the Board considers that variations in the measured values of the surface tension and of the contact angle would have a limited impact on the value of the penetration coefficient. This could possibly affect the precise definition of the boundaries of claim 1 with the consequence that it may be difficult to establish whether a given infiltrant is encompassed or not by the definition of component b) of claim 1. However, this issue does not relate to the assessment of sufficiency of disclosure.

3.6 As discussed in point 3.4 above, the description provides sufficient information on selecting the components of the infiltrant and example 3 discloses a method for its preparation. The other component of the kit of claim 1 is a conditioner based on a gel containing 5% hydrochloric acid. The Board sees no reason why a skilled person would not be able to prepare such a product.

Hence, the Board considers that the skilled person would be able to carry out the invention defined in the patent in suit. The requirement of sufficiency of disclosure is therefore met.

4. Remittal

4.1 Both opponents withdrew their oppositions in the course of the appeal proceedings (see point VII above). Pursuant to the second sentence of Rule 84(2) EPC, after withdrawal of the opposition(s) the EPO may continue the opposition proceedings of its own motion.

4.2 The main purpose of appeal proceedings is to review decisions of departments of first instance. In the

decision under appeal only the grounds for opposition pursuant to Article 100(b) and (c) EPC have been considered whereas the grounds of novelty and inventive step have not been dealt with. Under these circumstances the Board deems it appropriate to remit the case to the opposition division in order for it to decide whether to continue or close the opposition proceedings, pursuant to Rule 84(2) EPC.

Order

For these reasons it is decided that:

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

The Registrar:

The Chairman:



S. Fabiani

D. Boulois

Decision electronically authenticated