

A		B		C	X
---	--	---	--	---	---

File Number: T 298/90 - 3.3.2
Application No.: 81 305 295.8
Publication No.: 0 053 442
Title of invention: Dental compositions

Classification: A61K 6/06

D E C I S I O N
of 26 October 1992

Proprietor of the patent: Imperial Chemical Industries PLC
Opponent: 01 Etablissement Dentaire Ivoclar
02 Bayer AG, Leverkusen

Headword: Dental Composition/ICI
EPC Art. 56
Keyword: "Inventive step (yes) - non-obvious solution"



Case Number : T 298/90 - 3.3.2

D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 26 October 1992

Appellant : Etablissement Dentaire Ivoclar
(Opponent 01) FL-9494 Schaan (LI)

Representative : Uexküll & Stolberg
Patentanwälte
Beselerstrasse 4
W-2000 Hamburg 52 (DE)

Respondent : Imperial Chemical Industries PLC
(Proprietor of the patent) Imperial Chemical House,
Millbank
London SW1P 3JF (GB)

Representative : Kolker, Peter Leigh
Imperial Chemical Industries PLC
Legal Department: Patents
P.O. Box 6
Bessemer Road
Welwyn Garden City
Herts. AL7 1HD (GB)

Other party : Bayer AG, Leverkusen
(Opponent 02) Konzernverwaltung RP
Patente Konzern
Bayerwerk
W-5090 Leverkusen (DE)

Decision under appeal : Interlocutory decision of the Opposition Division
of the European Patent Office dated 12 December
1989, posted on 2 February 1990 concerning
maintenance of European patent No. 0 053 442 in
amended form.

Composition of the Board :

Chairman : A.J. Nuss
Members : I.A. Holliday
E.M.C. Holtz

Summary of Facts and Submissions

- I. European patent No. 0 053 442 was granted on the basis of sixteen claims contained in European patent application No. 81 305 295.8.

- II. Oppositions were filed against the granted patent by the Appellant (Opponent I) and Bayer AG (Opponent II). Of the documents cited in the course of the proceedings, the following remain relevant for the present decision:
 - (2) EP-A-0 013 491
 - (4) DE-A-2 405 578
 - (8) DE-A-2 705 220.

- III. In accordance with the interlocutory decision under appeal, the Opposition Division proposed to maintain the patent in amended form.

The Opposition Division mentioned two documents (4) and (2) as closest state of the art. Although the disclosure of (4) included compositions comprising mixtures of fillers of large particle size (up to 5 μm) and fine fillers (maximum 0.07 μm), the total amounts of filler employed were in general below that of the patent in suit. Furthermore, the sole example of (4) used only fine filler. Document (2) was concerned with the use of dispersing agents in the preparation of dental compositions. However, the compositions disclosed therein contain either fine or large particle size filler (in accordance with the definitions of the patent in suit) but not mixtures thereof. It was the Opposition Division's view that the combined teachings of (2) and (4) did not lead in an obvious manner to the compositions of the patent in suit.

- IV. The Appellant lodged an appeal against the said decision. Oral proceedings took place on 26 October 1992.

The arguments of the Appellant, both in the written procedure and at the oral proceedings may be summarised as follows.

Figures which had originally been presented by Opponent II were reproduced in order to show that there was an overlap between the ranges claimed in the patent in suit and those disclosed in document (4). From published figures of the densities of the resinous binder, the amorphous silica and borosilicate glass employed in the compositions of (4), the volume fractions of the large particle size and fine fillers were calculated at the extremes of the ranges assuming a 25% by weight content of the coarser filler. The calculations yielded a volume fraction range of 17.61-66.59% for the total filler and 14.07 to 60.42% for the fine filler compared with the respective ranges of 60-85% and 10-55% claimed in the patent in suit. In terms of these ranges, the Appellant argued that the sole feature which determined the novelty of the compositions of the patent in suit was the presence of dispersing agent. Comparative tests were filed which showed that the presence of a dispersing agent had a negligible effect on the physical properties of the product and could not therefore contribute to inventive step.

The Appellant further argued that it was entirely arbitrary whether one chose document (2) or document (4) as closest state of the art, but chose to start from (2). It was argued that (2) disclosed the same binder, catalyst and dispersing agent as the patent in suit and also the same types of filler. In relation to (2), the problem to be solved was to develop improved new dental compositions. The solution lay in the choice of mixtures of fillers

defined by volume fraction equations set out in Claim 1 of the patent in suit. The Appellant objected to the unusual parameters used to define the amounts of filler, arguing that the volume fractions expressed in Claim 1 were only used to present a more "exotic" image. It was also argued that the ranges claimed in the patent were too broad; 75% would be a practical upper limit for the total filler volume (cf. Example 6) and particles coarser than 5 μm would be too abrasive for use in dental compositions.

Document (2) disclosed in Example 20, a fine particle size silica filler, "Aerosil A130", also known as a reinforcing filler. Example 21 of (2) related to the use of cristobalite sand of particle size 5 μm , i.e. a large particle size filler in terms of the patent in suit. Thus, (2) disclosed all the features of the patent in suit including the actual fillers used except the use of mixtures of the said fillers. However, the skilled person would be aware from (4) (page 2) of the compromise of properties required in dental compositions between the ability to be polished and abrasion resistance. A high proportion of small sized filler enables the products to be polished and also contributes to the overall strength, whilst the coarser particles improve the abrasion resistance. The Appellant accordingly argued that it would have been obvious from a combination of the teachings of (2) and (4) to experiment with mixtures of fine and larger particle size fillers.

A further argument related to the Opposition Division's conclusion that the volume fraction ranges expressed in Claim 1 represented a selection within the teaching of (4) (paragraph 7.3 of the decision). Having regard to the overlap of ranges between (4) and the patent in suit, a selection could not be achieved by extending the ranges.

The Appellant also filed several post-published documents which compared the properties of "Occlusin", the product of the disputed patent, with other commercially available dental filling compositions. It was argued that these documents, from a variety of sources, provided more reliable comparisons than a document published by the Respondent which had been relied upon by the Opposition Division.

Finally, the Appellant argued that commercial success could never be an argument in favour of inventive step.

- V. The Respondent denied that there was any significant overlap between the ranges of the patent in suit and those disclosed in document (4). This argument was supported by three tables filed at the oral proceedings which related to the use of three large particle fillers having differing densities.

The Respondent denied that a combination of documents (2) and (4) foreshadowed the teachings of the disputed patent. The disclosure of (4) should be considered in relation to that of the later document (8) which acknowledged (4). According to (8), on no account should more than 5% by weight of fine fillers be used in dental compositions.

Contrary to the assertions of the Appellant, the comparative tests supplied showed "Occlusin" in quite a favourable light, which must have contributed to its commercial success.

The Respondent had never argued that the dispersing agent contributed to the physical properties of the products of the patent; it merely helped in dispersing the filler.

The volume fraction parameters were defended by the Respondent. When one was faced with the dispersion of large amounts of powder in relatively small quantities of liquid, it was the volume and not the weight which was important. Having regard to the negligible overlap between the prior art and the patent in suit, the volume fractions expressed by Claim 1 must be regarded as an inventive selection.

As an alternative to Claim 1 allowed by the Opposition Division, the Respondent filed on 1 October 1990 a main claim with essentially the same content but which was not set out in the two-part form.

VI. Claim 1 according to the main request reads as follows:

"1. A fluid dental composition which comprises liquid polymerisable material (A), filler (B), polymerisation catalyst for the polymerisable material and dispersing agent, characterised in that the filler consists essentially of a mixture of inorganic fillers in volume fraction from 60% to 85% where volume fraction is expressed as

$$\frac{(\text{volume B} \times 100)}{(\text{volume A} + \text{volume B})}$$

said mixture of fillers comprising fine particle size filler and large particle size filler, the fine particle size filler having a mean size value in the longest direction of less than 0.1 μm and being present in volume fraction from 10% to 55% where volume fraction is expressed as

$$\frac{(\text{volume fine} \times 100)}{(\text{volume A} + \text{volume fine})}$$

and the large particle filler having the mean size value in the longest dimension of 0.5 μm to 80 μm ."

- VII. The Appellant requested that the decision of the Opposition Division be set aside and that the patent be revoked.

The Respondent requested that the appeal be dismissed or alternatively that the patent be maintained on the basis of Claim 1 filed on 1 October 1990.

Reasons for the Decision

1. The appeal is admissible.
2. The Board has no reason to question the formal allowability of the amended claim acknowledged in paragraph 2 on page 3 of the contested decision.
3. The patent in suit relates to dental compositions, that is compositions comprising a polymeric binder and a mixture of inorganic fillers which harden rapidly and may be used as a substitute for amalgam in the filling of teeth.
 - 3.1 In the opinion of the Board, the closest prior art is document (4) which also relates to dental compositions comprising liquid polymerisable material and inorganic filler. In accordance with Claim 1 of (4), the filler consists of amorphous silica having a maximum particle size of 0.07 μm . According to Claim 3 of (4) and the corresponding description on page 3, up to 25% by weight of the filler may be replaced by glass particles, e.g. borosilicate glass, having a particle size up to 5 μm . The

hardened products are stated to have both a satisfactory bending strength and the ability to be polished.

- 3.2 In relation to (4), the problem to be solved is to obtain improved dental compositions, especially having good wear resistant properties suitable for use as posterior fillings, i.e. for molars.
- 3.3 The problem is solved by the compositions according to Claim 1 which contain a mixture of fine particle size filler and large particle size filler which satisfy the volume fraction requirements defined therein.
- 3.4 At first sight, the patent in suit might seem deficient in failing to provide any comparative experiment with the closest state of the art (cf. decision T 181/82, OJ EPO 1984, 401). However, comparative Example 7 shows that when working just outside the ranges of volume fraction specified by Claim 1, unsatisfactory results are obtained, in particular poor wearing properties. In accordance with decision T 197/86 (OJ EPO 1989, 371; Reasons points 6.1.2 and 6.1.3) together with unpublished decision T 35/85 dated 16 December 1986 (Reasons point 4), referred to therein, voluntary comparisons with art closer than that of the nearest prior art may be sufficient for the patentee to discharge his burden of proof.
- 3.5 Having regard to these experiments, the Board is satisfied that the problem has been plausibly solved.
- 3.6 The Appellant's criticism that the ranges are too broad (cf. point IV, paragraph 4 above) does not affect this conclusion; in the absence of any supporting evidence, this amounts to mere allegation. Accordingly, since the Appellant has failed to discharge the onus of proving the said facts, any argument based thereon cannot be accepted

(cf. T 219/83, OJ EPO 1986, 211 and T 78/85 of 1 October 1986 (Reasons, point 6)).

4. Irrespective of whether or not an overlap exists between the ranges of fillers disclosed in document (4) and those of the patent in suit, novelty of the subject-matter of Claim 1 is established by the presence of a dispersing agent. Since novelty is not in dispute it is not necessary to consider the matter any further.

5. It remains to consider whether or not Claim 1 satisfies the requirements of Article 56 EPC in respect of inventive step.
 - 5.1 The patent in suit differs from the closest prior art (4) in two respects. Firstly the compositions presently claimed contain a dispersing agent and secondly the permissible amounts of total filler and of fine particle size filler are expressed in quite different manners. The Appellant has argued that the ranges expressed by weight in document (4) overlap to a considerable extent, the ranges expressed in terms of volume fractions in the disputed patent. If the subject-matter of Claim 1 of the patent in suit amounted to nothing more than the mere addition of a dispersing agent known from document (2) to the same dental compositions known from (4), the Board would indeed have sympathy for the arguments of the Appellant.

 - 5.2 However, the Respondent had argued during the opposition procedure that the ranges first provided by Opponent II were an oversimplification and that little or no overlap actually occurred. This argument was supported by the three tables supplied at the oral proceedings before the Board. The said tables demonstrate that there is only a minimal overlap between the filler content disclosed in

document (4) and those of the patent in suit. Each table covers a weight range of total filler from 80-30% and correspondingly 20-70% of resin of which 25% by weight of the filler consists of large size particles in accordance with the disclosure of (4). Each table assumes a density of 2.2 for the fine filler (amorphous silica) and respective densities of 2.2, 2.4 and 3.1 for the coarse filler. These correspond to materials actually used in the patent in suit, the figure of 3.1 relating to barium borosilicate, a radioopaque filler favoured by the Respondent and used in Example 6 of the patent. Only Tables 1 and 2 show any overlap at all; the overlap occurs at a total filler content of 76%w in each case. There is no overlap at filler contents of 74%w and 78%w nor at any other point in the range. It must be added that the tables supplied by the Respondent are confirmed by calculations made independently by the Board. It is therefore clear that the overlap is purely incidental depending upon the densities of the materials used.

5.2.1 Thus, although document (4) contains a clear teaching to employ mixtures of fillers having fine and large particle sizes in dental compositions, there is no hint to use such mixtures in the proportions set out in Claim 1 of the patent in suit.

5.2.2 Since the ranges known from (4) and those of the patent in suit are so different, the addition of a dispersing agent known from document (2) to the compositions known from (4) cannot lead to the compositions currently claimed. There is also no incentive from (2) alone to use mixtures of fillers. Examples 20 and 21 of (2) use individually the fillers silica ("Aerosil A130") and Cristobalite sand, which respectively fall within the definitions fine and large particle size fillers according to the patent in suit. However, the composition of Example 20 is stated to

be useful as a denture base, clearly a different requirement from that of a tooth filling composition. Example 21 uses methyl methacrylate monomer which, as the Respondent pointed out at the oral proceedings, would be wholly unsuitable for use in the mouth. There is accordingly no incentive in (2) to use mixtures of fillers in any proportion, together with a dispersing agent, in order to prepare a dental composition.

5.2.3 The disclosure of document (8), which acknowledges (4) as prior art (page 7, lines 20-22) and was published some two years thereafter, must also be taken into consideration. According to (8), the use of small particle size fillers in terms of the disputed patent should be avoided. If fillers of less than 0.2 μm are employed, this should be in amounts less than 5% by weight; in such proportions they are useful as thickening agents (page 9, lines 22-25). Accordingly, even taking the disclosure of (4) into consideration, the inventors of (8) showed no inclination to use mixtures of small and large particle size fillers in terms of the patent in suit.

5.2.4 It is apparent from the preceding that the volume fractions employed in Claim 1 of the patent in suit, although unusual parameters vis-à-vis the prior art, are not in any way intended to disguise a known teaching. The Board accepts the Respondent's argument that, when faced with the problem of dispersing large amounts of solid particles in a small amount of solvent, the volume is more important than the weight. It also seems to the Board that, in relation to the filling of a tooth cavity, the volume of the respective materials is the more important factor.

5.3 Accordingly, in the judgment of the Board, the compositions presently claimed in terms of volume

fractions of total filler and fine filler must be considered to solve the underlying problem in a non-obvious manner despite the possibility of incidental overlap with the closest state of the art. It has been shown that the said prior art contains no information on the basis of which the skilled person would have suspected that, by working inside certain narrowly defined ranges of filler materials, improved dental compositions might have been achieved. Under these circumstances, the claimed compositions show - as far as overlapping ranges of filler materials are concerned - the quality of a non-obvious selection.

- 5.4 In the course of the proceedings, a number of documents have been filed which compare the properties of "Occlusin", a product of the Respondent prepared in accordance with the patent in suit, with other commercially available dental compositions. These documents need not be considered in relation to the patentability of the claimed subject-matter since technical progress is not a requirement of the EPC. Technical superiority may be indicative of the presence of inventive step if it specifically relates to the solution of the problem arising in relation to the closest state of the art. However, technical progress in comparison with other marketed products cannot be a substitute for the demonstration of inventive step with regard to the closest state of the art (cf. decision T 164/83, OJ EPO 1987, 149, Reasons, point 8).
6. It is apparent that the prior art cited by the Appellant does not prejudice the maintenance of the patent in the amended form allowed by the Opposition Division. It is therefore unnecessary for the Board to consider the alternative claim submitted by the Respondent.

Order

For these reasons, it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

P. Martorana

A.J. Nuss